



U.S. Department of Energy
Office of Civilian Radioactive Waste Management



DOE/NRC Quarterly Quality Assurance Meeting

Rockville, Maryland

February 18, 2004





U.S. Department of Energy
Office of Civilian Radioactive Waste Management



Quality Assurance Overview Exhibits

Presented to:

DOE/NRC Quarterly Quality Assurance Meeting

Presented by:

R. Dennis Brown

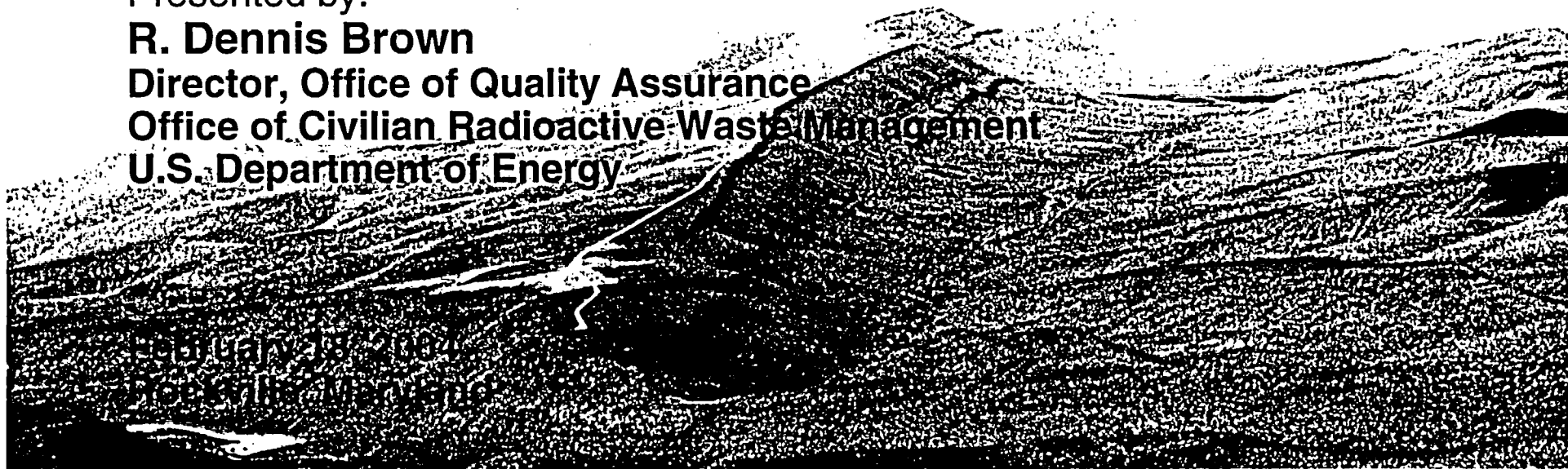
Director, Office of Quality Assurance

Office of Civilian Radioactive Waste Management

U.S. Department of Energy

February 18, 2004

Office of Civilian Radioactive Waste Management



2.4.2.1 Percentage of Adverse Conditions Self-Identified

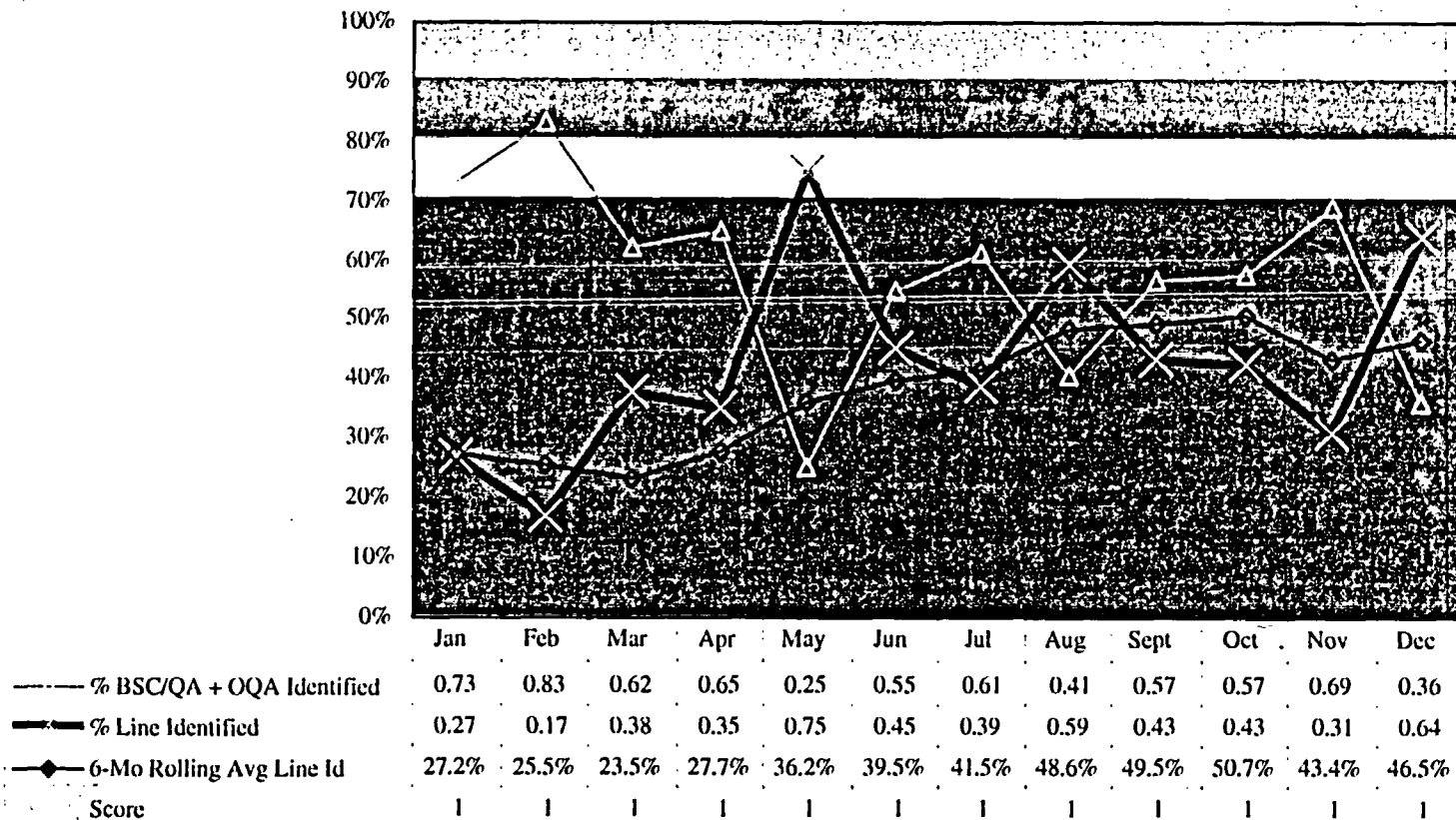
To measure the overall effectiveness of the self-reporting.

Score: 1.00



2.4.2 Self-Reporting Culture

2.4.2.1 Adverse Conditions (Q-CRs) Self-Identified
Jan - Dec 2003

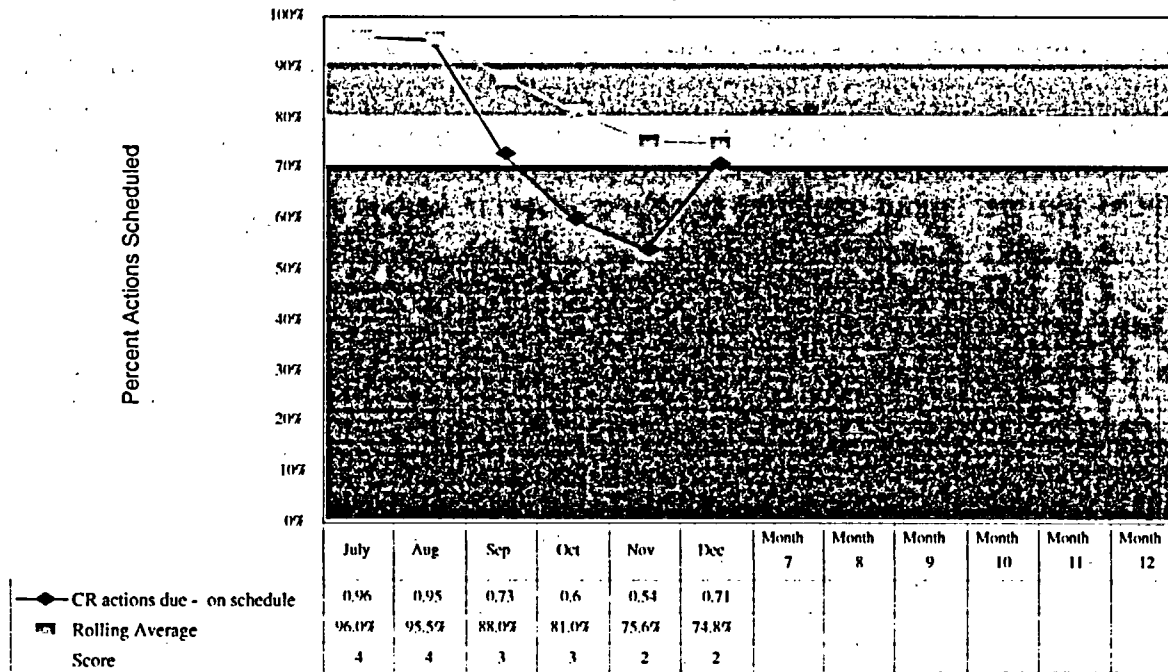


2.4.4.3 Condition Report Action Implementation Timeliness: Leading indicator that assists management in determining if problems are occurring relative to ability of organization to meet the performance goals related to age of open condition reports (CRs). This indicator measures the organization's ability to complete individual actions in a timely manner.

Score: 2.00

Y

2.4.4 Timely Corrective Action & Resolution
2.4.4.3 Condition Report Action Implementation Timeliness (.30)
July - Dec 2003



Analysis: Although performance is still below goal, this month showed a positive increase over the past two months. The majority of late actions are noted as completion of the plan and implementation of the corrective actions to close the CR. The high number of conditions issued and subsequent increasing backlog are in direct correlation to the increased number of late corrective actions during the month. Some late actions continue to be due to user's unfamiliarity with the new system and time required during evaluation and planning which on clarification or extent of the issue.

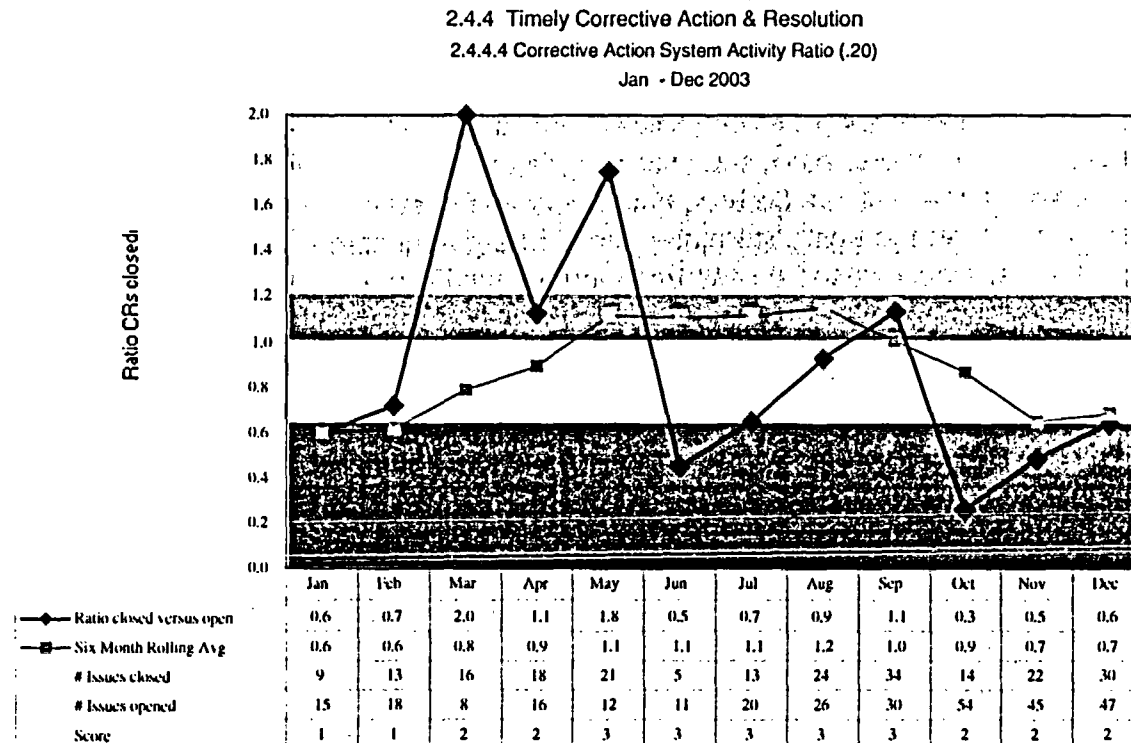
Corrective Action (CA): Late actions are addressed as a priority issue in weekly senior management and departmental management weekly meetings to provide support and reinforce the commitment to timeliness for all steps throughout the corrective action process.



2.4.4.4 Corrective Action System Activity Ratio: To measure number of issues opened each month as compared to number of issues closed during same period. Effective CA system substantially closing more issues than are opened, reducing backlog open issues. Low closure rate compared to issues opened implies system not functioning.

Score: 2.

Y



Analysis: The ratio for closed CRs rose slightly in December 2003 with the 6-month average remaining flat. Closures have risen consistently over the past 3 months repeating the number/pattern of closures during the last quarter of FY03 indicating more efficiency with use of the system and revised process. However, there were twice as many Quality CRs issued from October-December as were issued during the last quarter of FY03, which leaves a greater backlog requiring action. Failure to make progress in reducing the number of condition reports can result in additional schedule delays and increased project costs.

Corrective Action: Condition reports and related corrective plans and actions are reviewed weekly with senior management to focus on timely and adequate development and closure. Coordinating similar actions for different issues is also providing better ability to implement corrective actions and complete closure.





U.S. Department of Energy
Office of Civilian Radioactive Waste Management



Corrective Action Program

Presented to:

DOE/NRC Quarterly Quality Assurance Meeting

Presented by:

Kerry M. Grooms

Office of Civilian Radioactive Waste Management

U.S. Department of Energy

February 17, 2004

Rockville, Maryland

Corrective Action Program

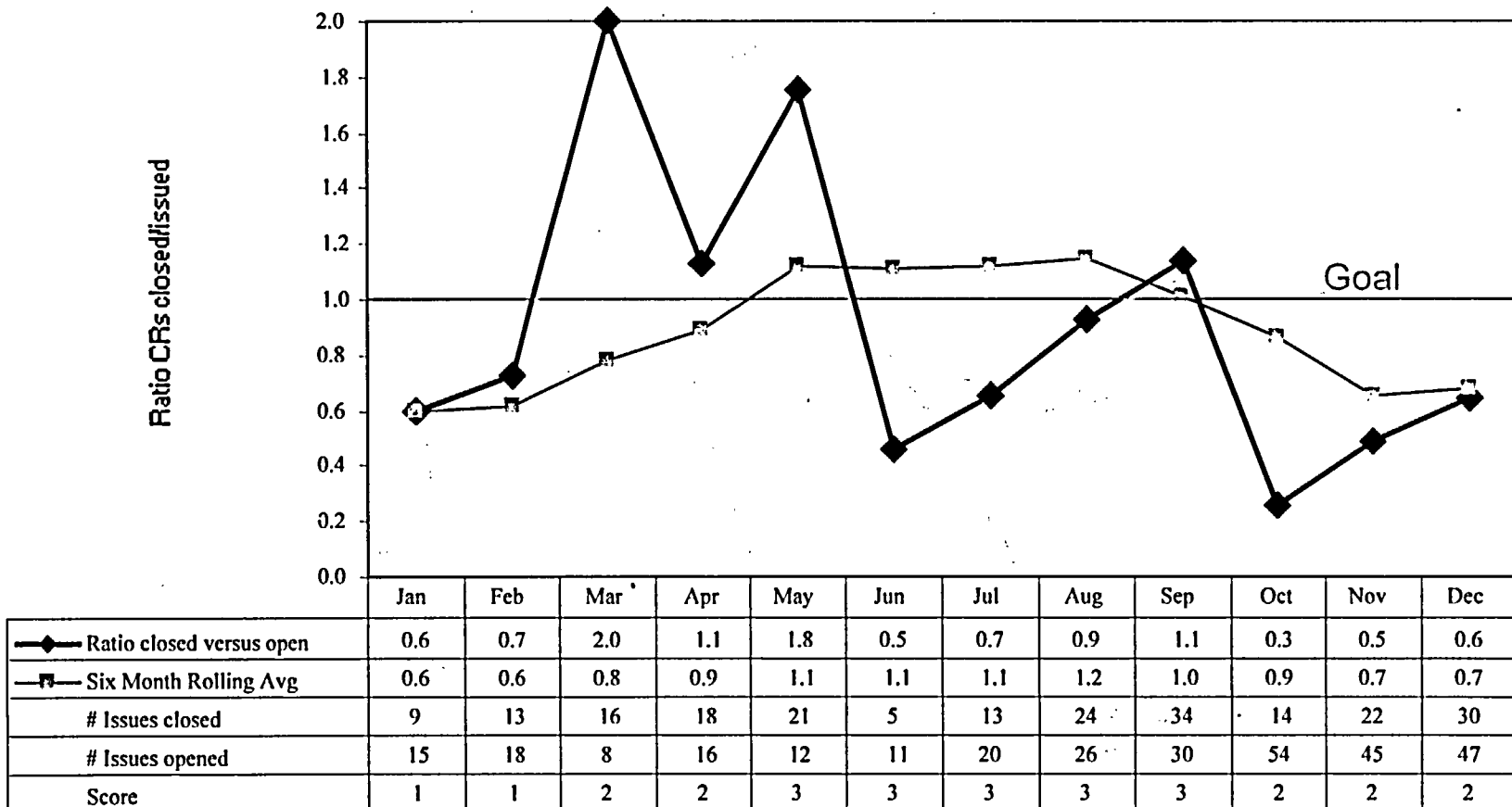
- **Current Status**
 - **New single program implemented**
 - **Increased Management Oversight**
 - ♦ **Corrective Action Program (CAP) Oversight Committee**
 - » **BSC Senior Management meeting**
 - » **Reviews Open Condition Reports (CR)**
 - » **Facilitates Processing of Condition Reports**
 - » **Holds Owners Accountable**
 - **Monitoring effectiveness and performance**



Corrective Action Program

(Continued)

Corrective Action System Activity Ratio
Performance Indicator 2.4.4.4

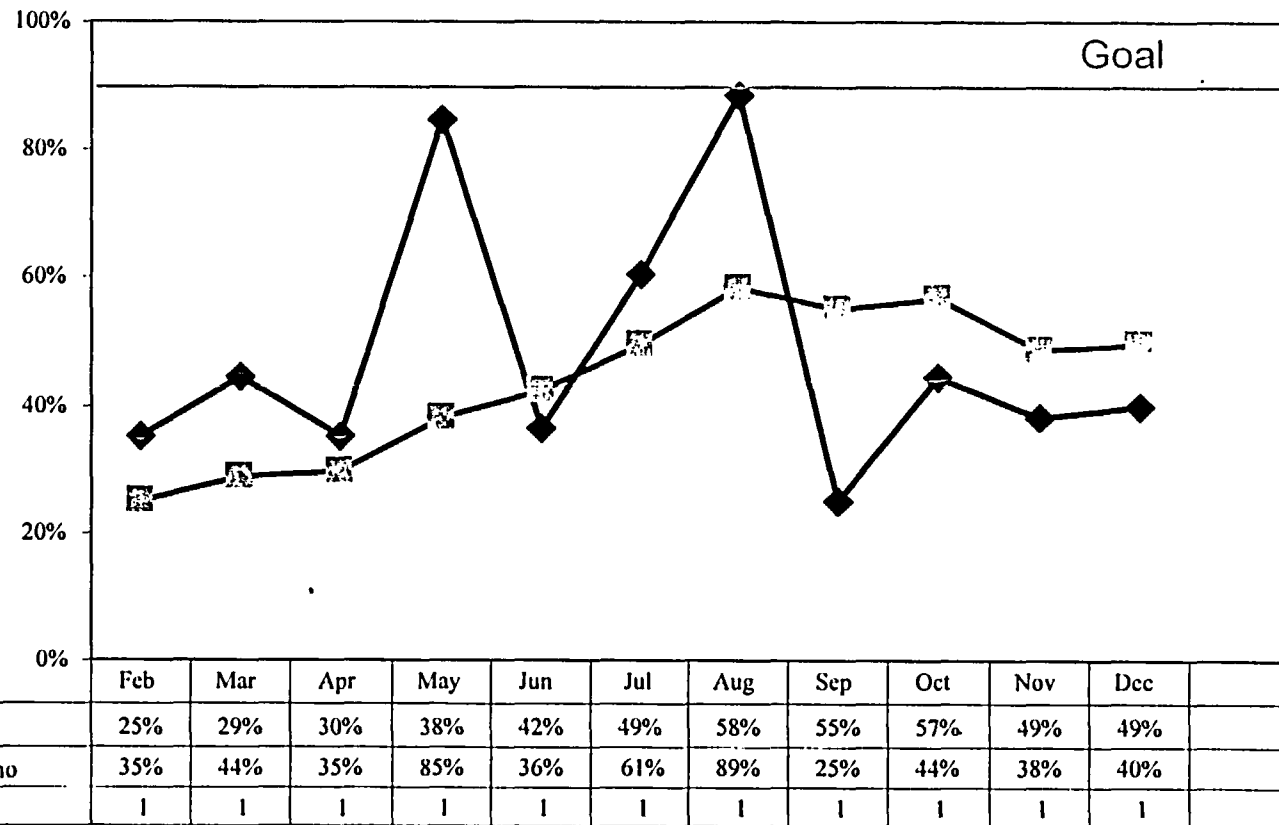


Corrective Action Program

(Continued)

Timely Corrective Action Plans
Performance Indicator 2.4.3.2

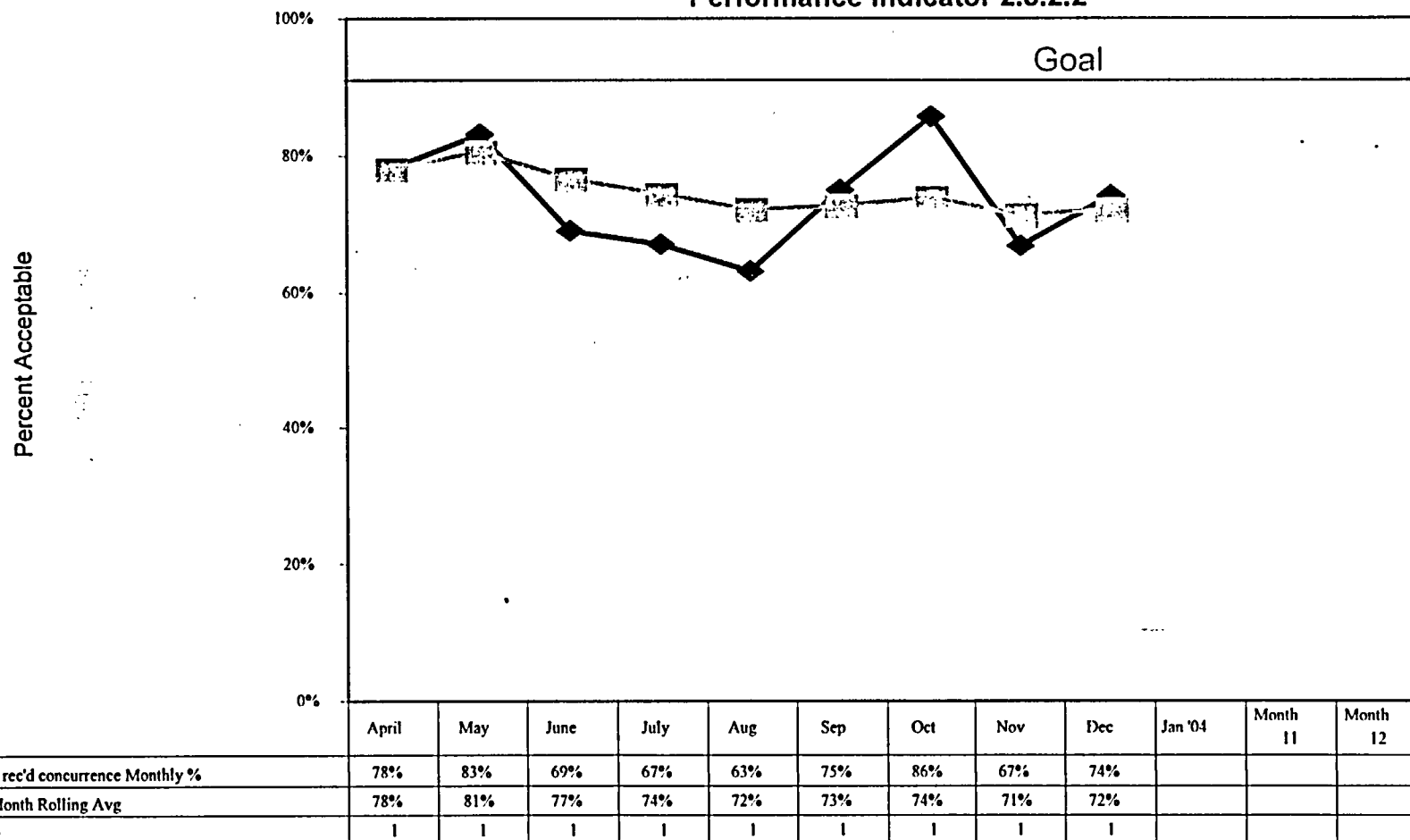
CA Plans Completed w/in 30 days



Corrective Action Program

(Continued)

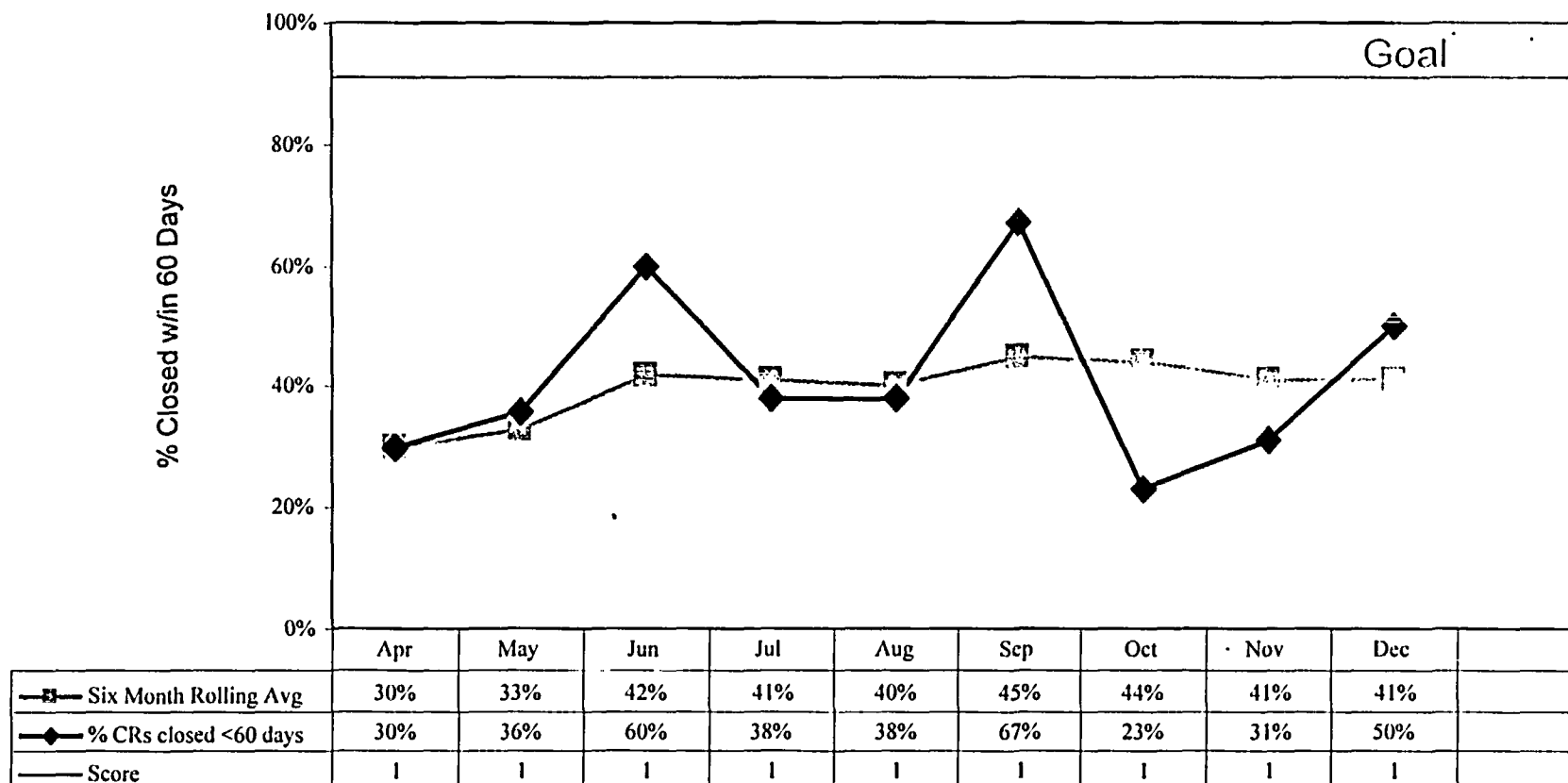
Acceptable Corrective Action Plans Developed for Quality (Q)
Level A & B CRs
Performance Indicator 2.3.2.2



Corrective Action Program

(Continued)

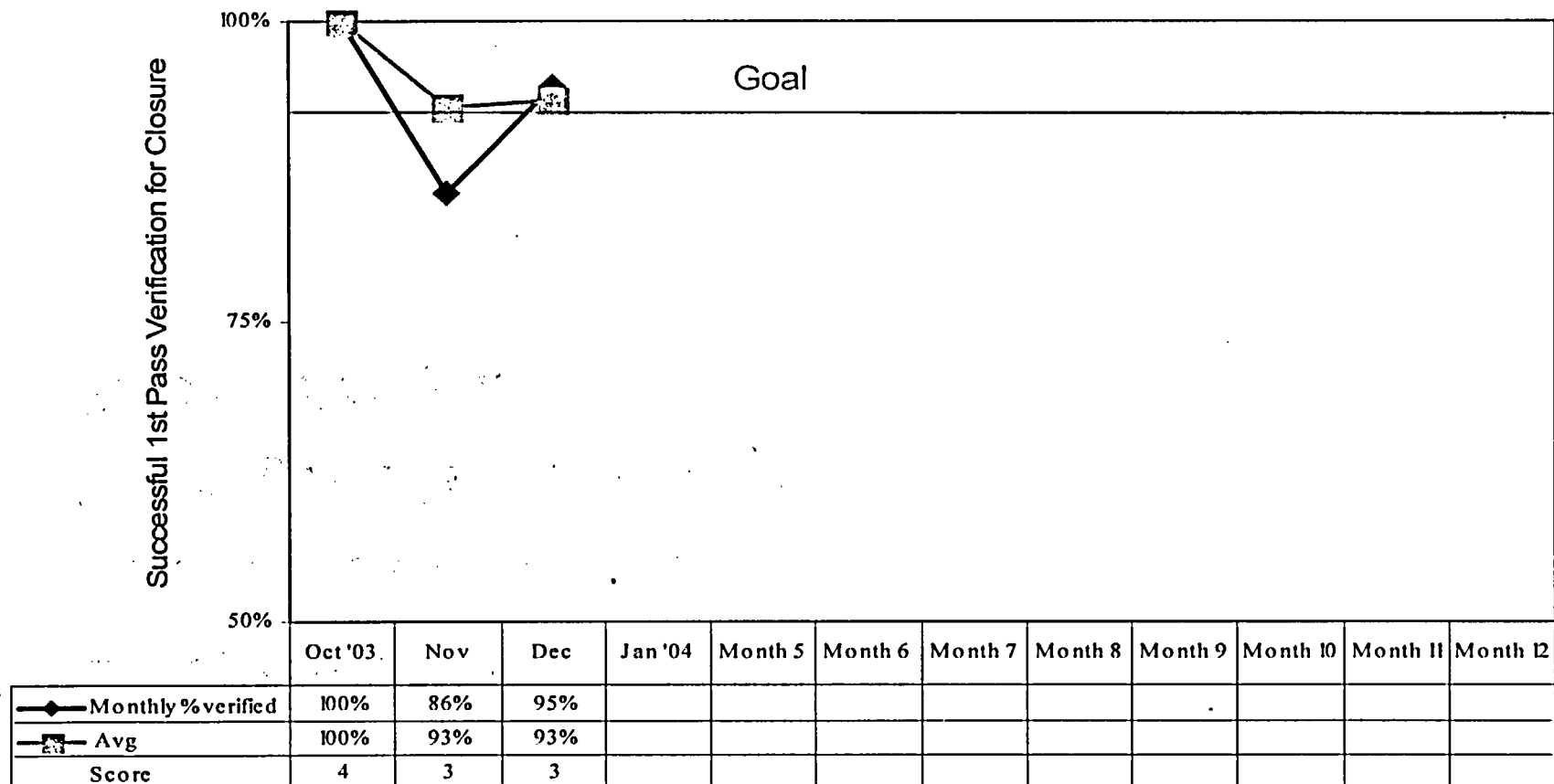
60-day Closure of Q Level B CRs
Performance Indicator 2.4.4.1



Corrective Action Program

(Continued)

Successful Corrective Action Verification
Performance Indicator 2.3.2.3



Corrective Action Program

(Continued)

- **Line Organization Assessments**
 - Review of Cause Coding
 - Training Needs Assessment
 - Process Analysis



Corrective Action Program

(Continued)

- **Quality Assurance Surveillances**
 - **Condition Report Screening**
 - ♦ **One condition adverse to quality (CAQ) identified - Issue was the cause codes assigned to Condition Reports**
 - **Corrective Action Program Evaluation Process**
 - ♦ **In Progress**
- **Quality Assurance Audit**
 - **Scheduled for July 2004**



Corrective Action Program

(Continued)

- **Enhancements under review**
 - Revised Significance Levels
 - Simplified Process
 - Improvements to the tool



Corrective Action Program

(Continued)

- **Path Forward**
 - **Continue to monitor effectiveness and performance**
 - **Implement enhancements**
 - **Continue management involvement**
 - **Moving more accountability to the line organizations**





U.S. Department of Energy
Office of Civilian Radioactive Waste Management



Human Performance Issues

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Dennis C. Sorensen
Manager, Organizational Assurance
Bechtel SAIC Company, LLC

Rockville, Maryland

Human Performance Issues

- **Condition Report (CR)-1497 issued as Level B***
 - No adverse trends found per criteria in AP-16.3Q, *Trend Evaluation and Reporting*
 - Pattern of errors found
- **Dominant Contributors**
 - 90 percent of all CRs related to:
 - ♦ Human performance (40 percent)
 - ♦ Management (26 percent), and
 - ♦ Communications (24 percent)
 - Over 50 percent of causal factors found: Performance Assessment, Operations, and Design

*Condition Adverse to Quality



Human Performance Issues

(Continued)

- **Dominant Contributors** (Continued)
 - Human performance causes in contributing organizations were primarily skill-based errors
 - ♦ Skill-based: Slip or lapse
 - ♦ Rule-based: Rules applied incorrectly
 - ♦ Knowledge-based: Inadequate knowledge or unfamiliarity
- **Dominant Factors**
 - Less-than-adequate self-checking
 - Omitting steps in the procedure



Human Performance Issues

(Continued)

- **Barriers to prevent or reduce human error less than adequate**
- **Results from FY04 1st quarter trend analysis do not deviate significantly from the FY03 4th quarter results**
- **Actions to prevent**
 - **Implement pre-job briefings**
 - ♦ **Communicate linkage of task to the critical mission**
 - ♦ **Summarize critical steps**
 - ♦ **Identify likely errors and best work practices for self-identification**



Human Performance Issues

(Continued)

- **Implement pre-job briefings (Continued)**
 - ♦ Reinforce accountability for procedure compliance
 - ♦ Establish expectation for timely self-reviews
- **Share Lessons Learned**
 - ♦ Develop lessons learned related to human performance situations
 - ♦ Involve workers in sharing the learning of these errors
 - ♦ Develop and track specific actions
- **Enhance training**
 - ♦ Ensure rule-, knowledge-, and skill-based errors associated with the identified activities are addressed in the training modules



Human Performance Issues

(Continued)

- Enhance procedure for end-user
 - ♦ Simplify steps and actions
 - ♦ Provide notes to clarify expected actions
 - ♦ Clearly define roles and responsibilities

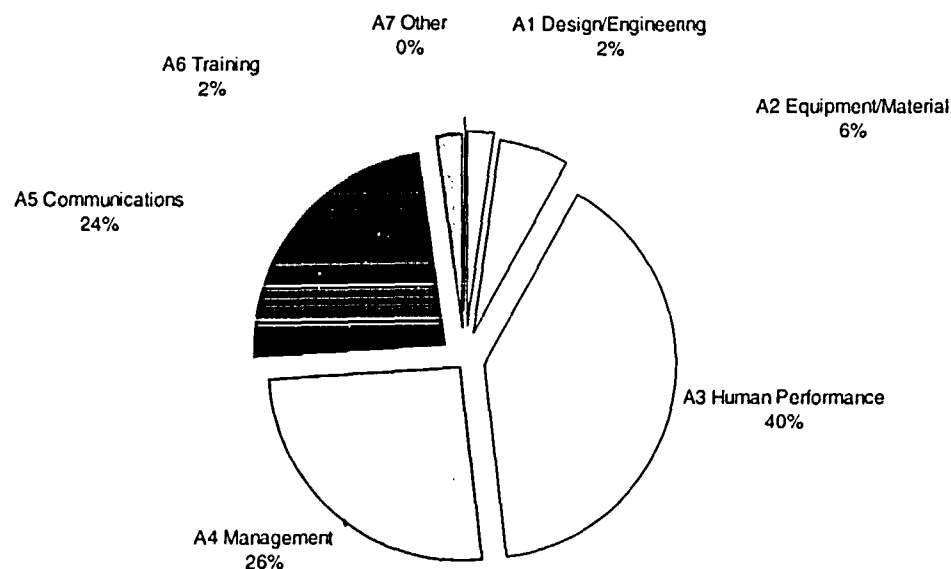


Backup



Trend Results

Fiscal Year (FY) 03 Trend Results



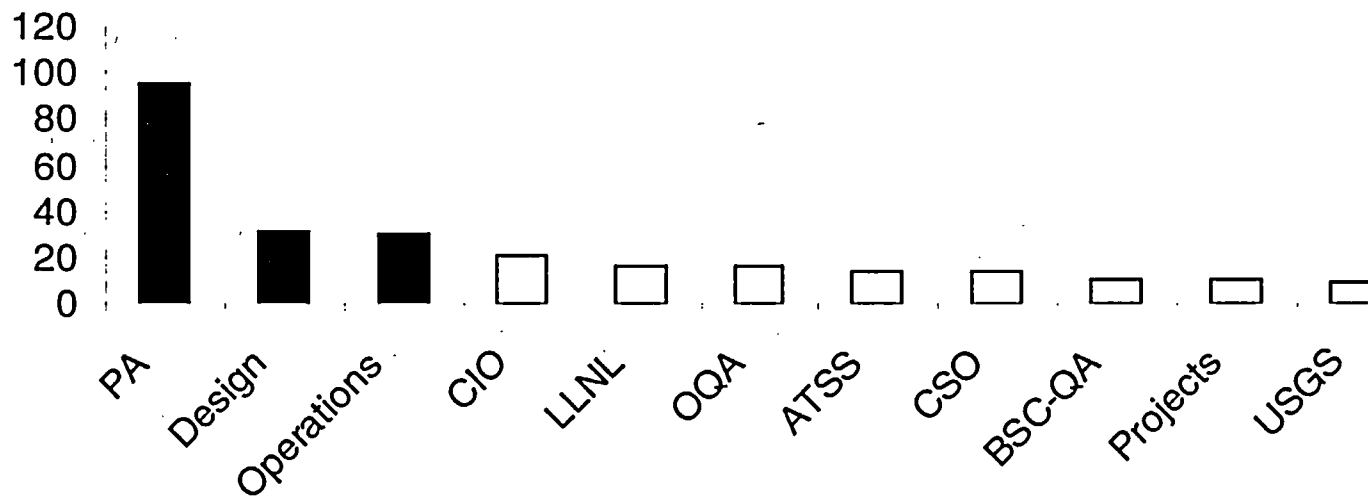
**Distribution of cause categories for FY03
condition reports observed in OCRWM activities**



Trend Results

(Continued)

FY03 Trend Results



Pareto chart of the distribution by organization of causal factor counts



Trend Results

(Continued)

FY03 Trend Results

Organization	Principal Cause Category					
	A1 Design Engineering	A2 Equipment/ Material	A3 Human Performance	A4 Management	A5 Communications	A6 Training
Performance Assessment (PA)	0	2	43	25	23	0
Repository Design (Design)	6	1	10	6	8	0
Site Operations (Operations)	1	4	9	6	9	1

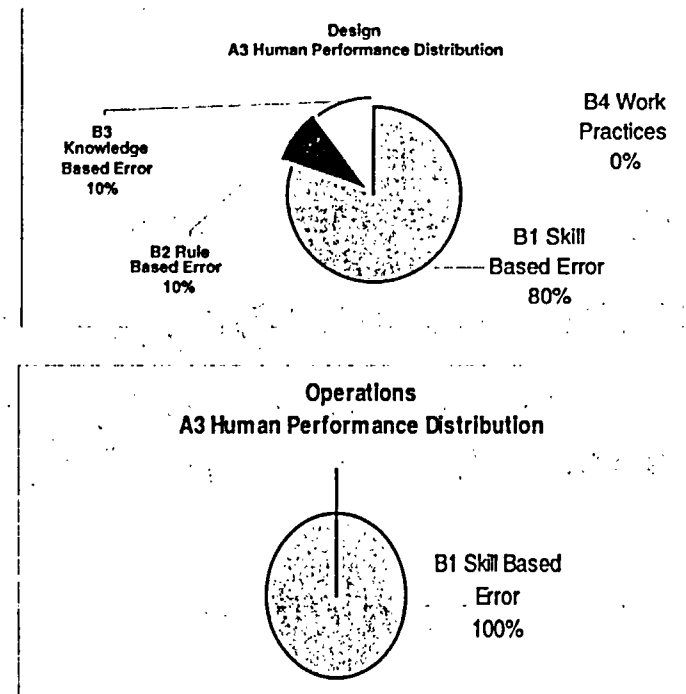
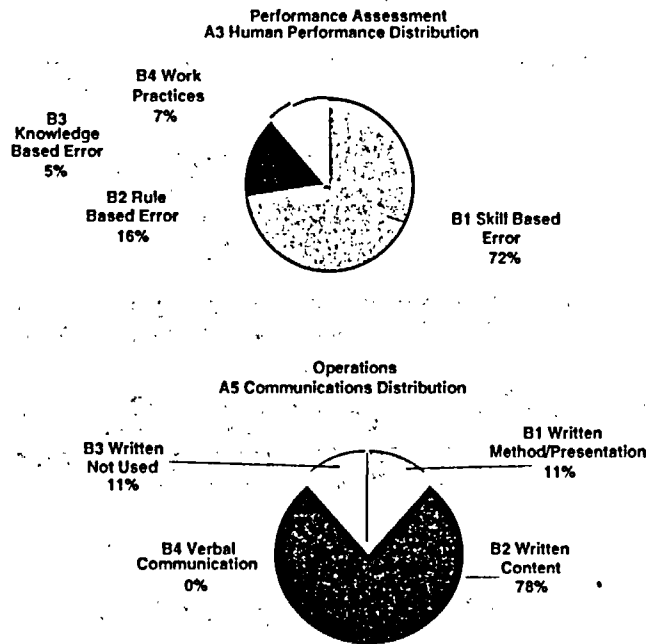
**Distribution of principal causal factors for
each of the selected organizations**



Trend Results

(Continued)

FY03 Trend Results



**Distribution of most observed causal factors
by selected organization**



Activities

- **Activities identified**
 - **AP-3.15Q, *Managing Technical Product Inputs* (rule-based errors)**
 - **AP-12.1Q, *Control of Measuring and Test Equipment and Calibration Standards* (knowledge-based errors)**
 - **AP-17.1Q, *Records Management* (skill-based errors)**
 - **AP-5.1Q, *Procedure Preparation, Review, and Approval* (skill-based errors)**
 - **AP-SIII.10Q, *Models* (skill-based errors)**
 - **AP-SI.1Q, *Software Management* (procedure content problems)**





U.S. Department of Energy
Office of Civilian Radioactive Waste Management



Quality Assurance Performance Indicators

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Michael E. Ulshaefer
Team Lead, Office of Quality Assurance
Office of Civilian Radioactive Waste Management
U.S. Department of Energy

February 19, 2003
Rockville, Maryland

Introduction

- **Purpose of Performance Indicators**
 - Provide insight into areas needing improvement
 - Provide an objective reference as a basis for management decisions
 - Focus on critical areas that can impact the mission



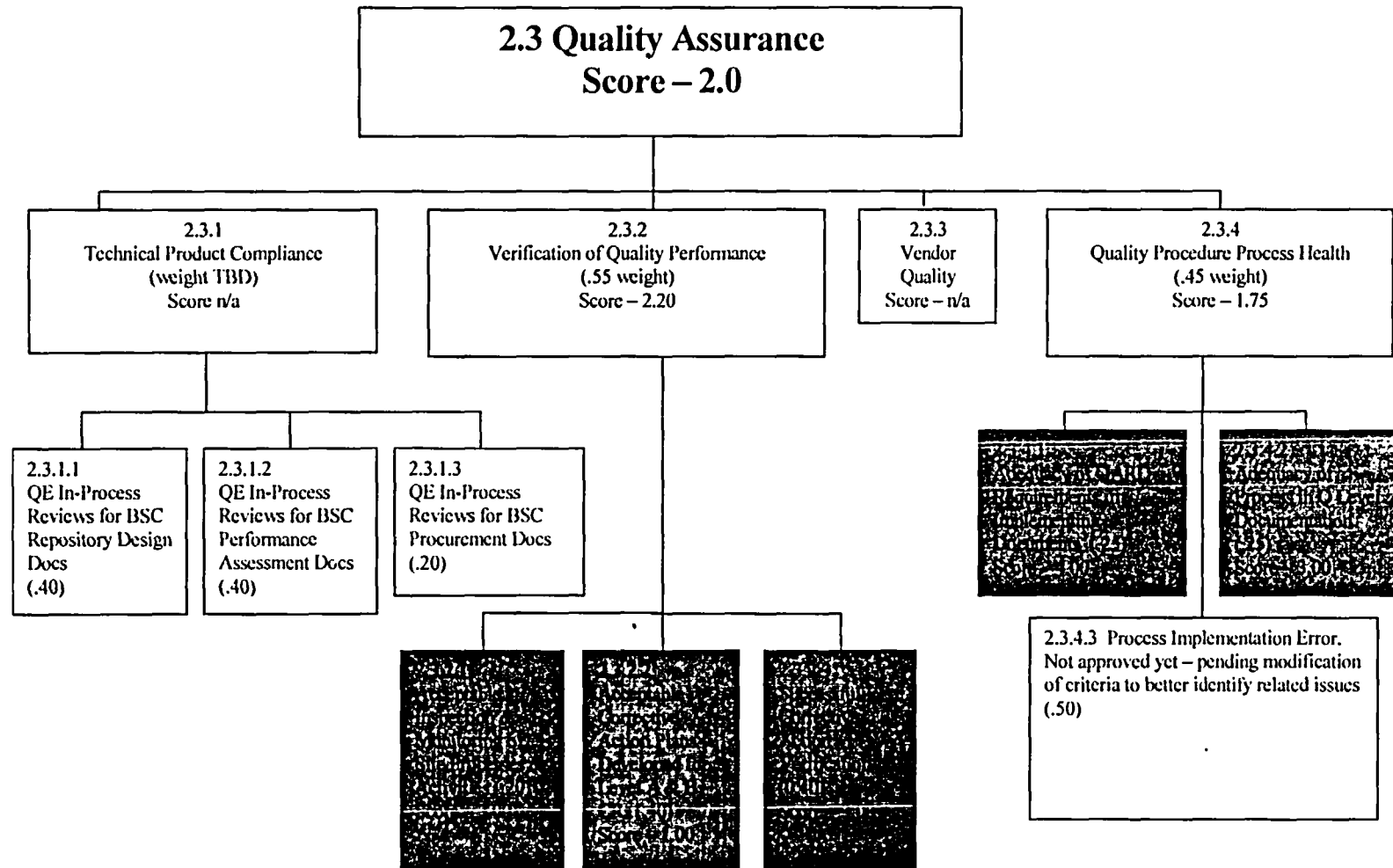
YUCCA MOUNTAIN PROJECT

Structure and Development of Performance Indicators

- **Three-tiered structure with increasing levels of detail**
- **Weights are subjective and approved by Senior Management**
- **Reported monthly at the Monthly Operating Review**
- **Quality Assurance (QA) Performance Indicators continue to evolve**
- **We will keep NRC informed as we develop and refine the indicators**



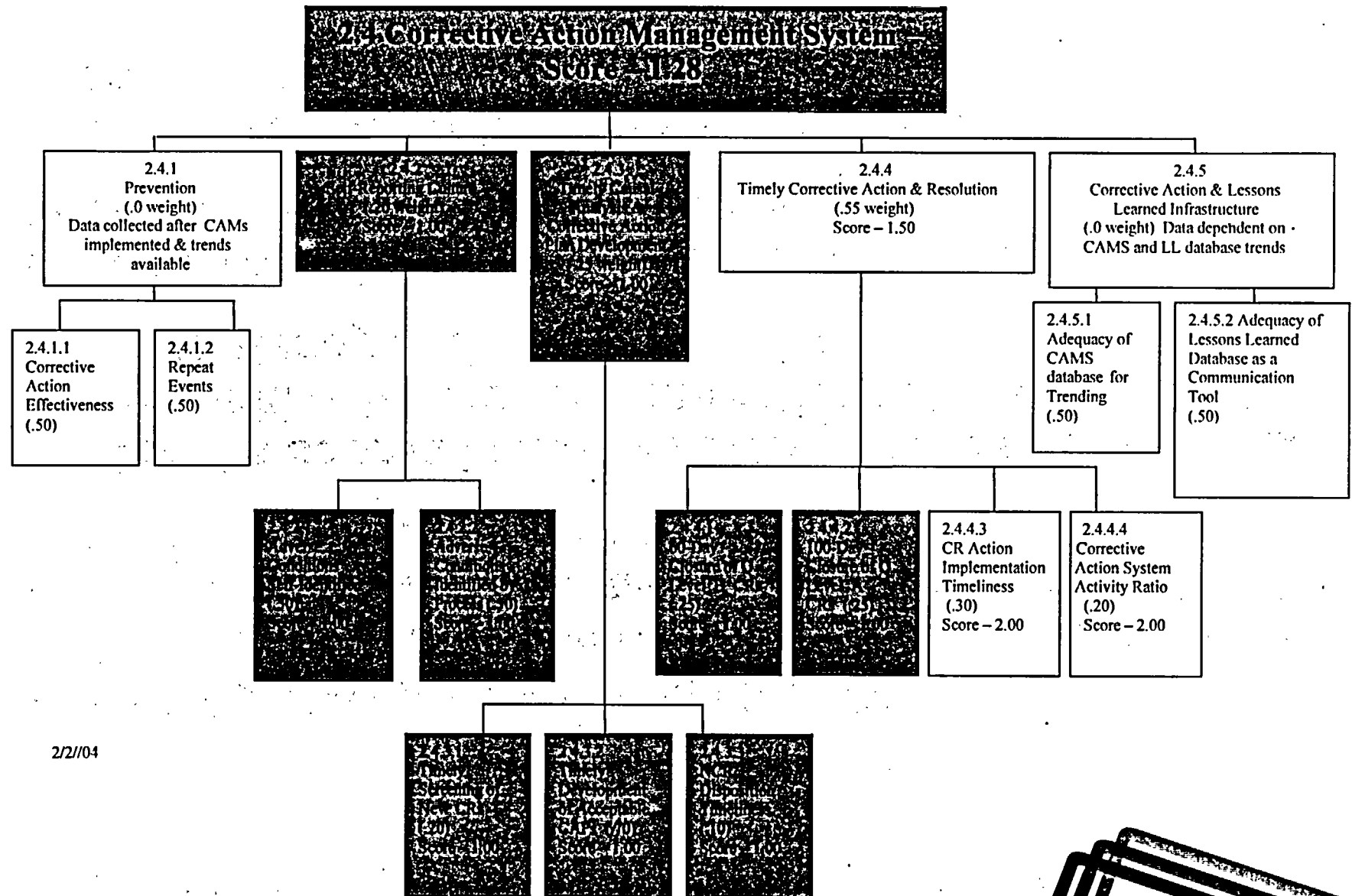
December Performance Indicators



2/2/04

December Performance Indicators

(Continued)



2/2/04



Performance Indicators - Summary

- **Eleven QA Performance Indicators (PIs) scored in the RED. Six out of the eleven show positive trends after the rollout of the new Corrective Action Program (CAP). Two are steady and three are negative**
- **Six QA PIs scored in the YELLOW. Three out of the six show positive trends after the rollout of the new CAP. Two are steady and one is negative**
- **Provides a self-critical snap shot of the Project's implementation of QA requirements**
- **Intended as the Project's Management Tool that provides bases for making decisions**



Backup



2.3 Quality Assurance

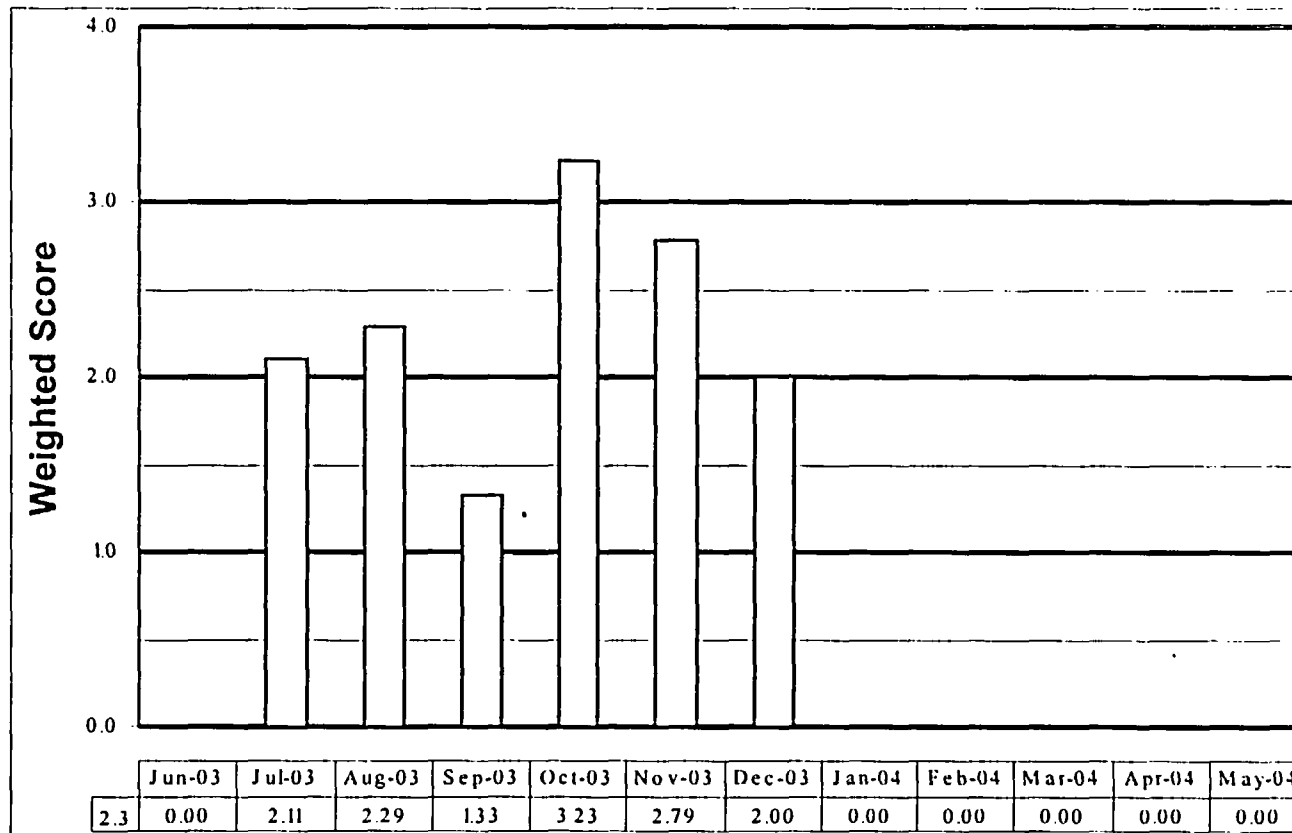
Measurement of Project implementation of a quality program.

Score: 2.00



Contributing Subareas Input

Input	Weight	Value	
2.3.2	55	2.20	Y
2.3.4	45	1.75	Y



2.3.2 Verification of Quality Performance

Measurement of accountability of the Line Organizations in implementing Project quality requirements.

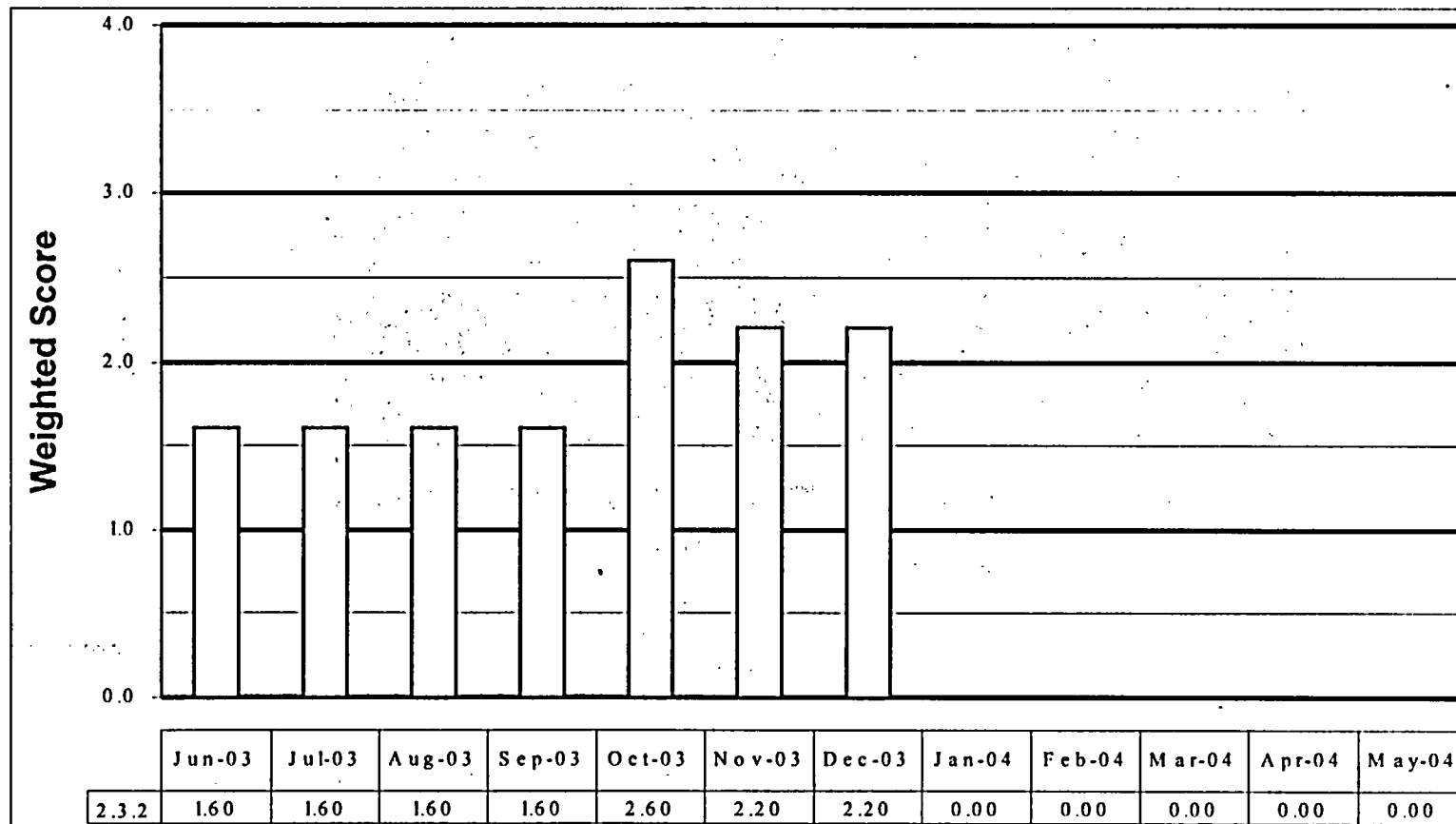
Score: 2.20



Contributing Subareas Input

Input	Weight	Value
2.3.2.1	20	3.00
2.3.2.2	40	1.00
2.3.2.3	40	3.00

GRG



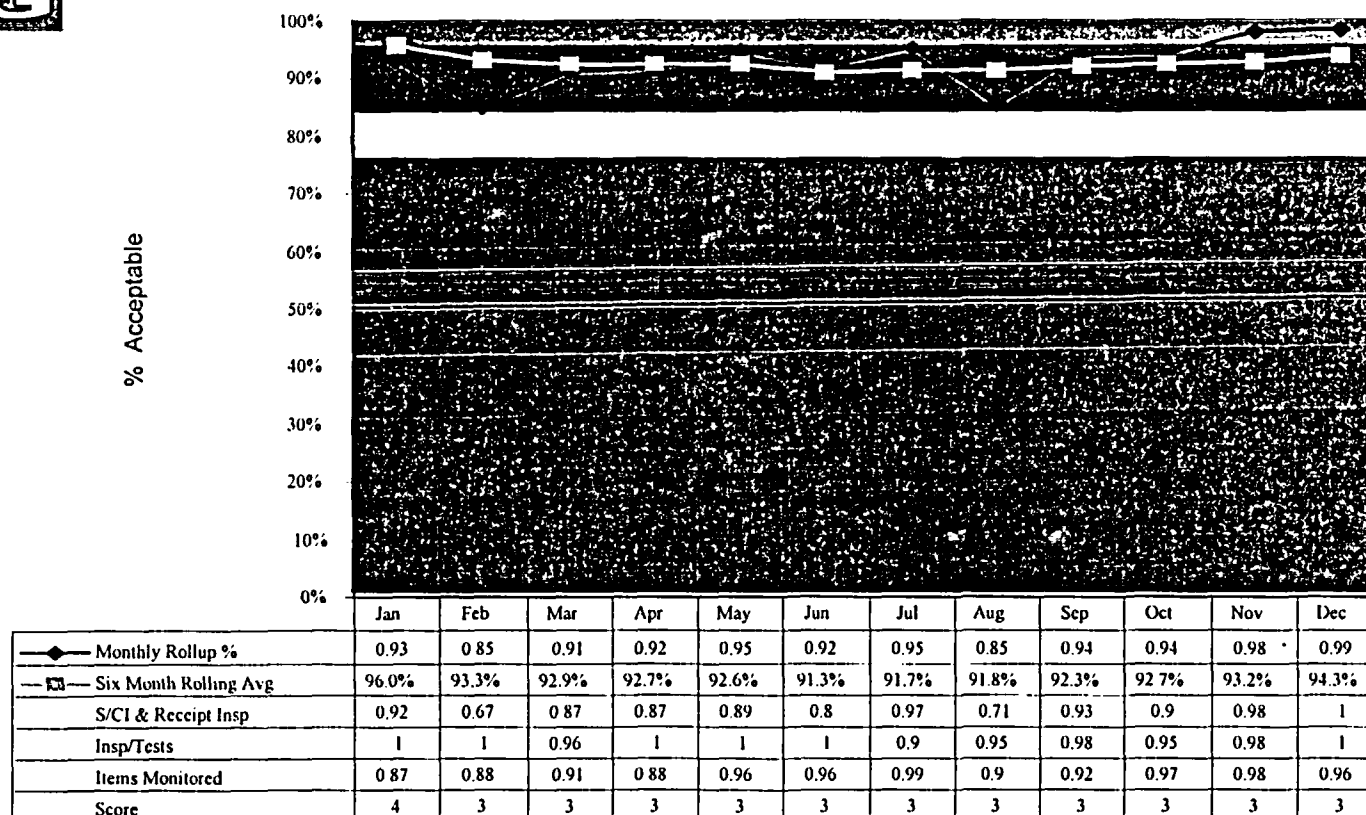
2.3.2.1 Acceptable Inspection and Monitoring of Site Processes and Activities

Illustrate effectiveness, efficiency, and adequacy of site processes and activities.

Score: 3.00



2.3.2 Verification of Quality Performance
Acceptable Performance/Compliance Inspection & Monitoring of Site (.20)
January - December 2003



2.3.2.2 Percentage of Approved Corrective Action Plans Developed for Level A & B Condition Reports

To measure quality of causal analysis and CA plan development process.

Score: 1.00

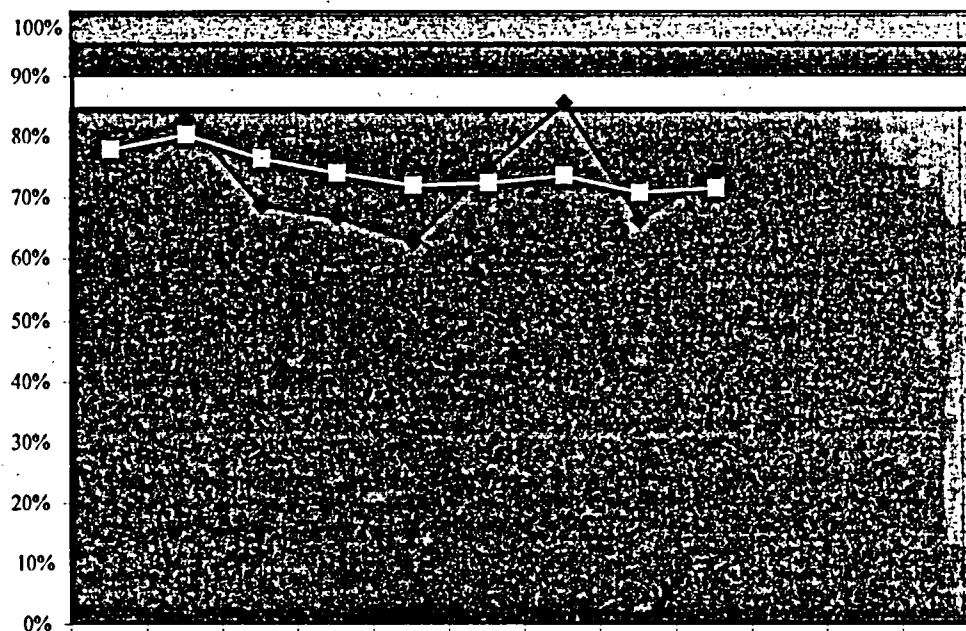


2.3.2 Verification of Quality Performance

2.3.2.2 Acceptable Corrective Action Plans Developed for Level A & B CRs (.40)

April - Dec 2003

Percent Acceptable



	April	May	June	July	Aug	Sep	Oct	Nov	Dec	Month 10	Month 11	Month 12
◆ Plans Rec'd Concurrence Monthly %	78%	83%	69%	67%	63%	75%	86%	67%	74%			
□ Six Month Rolling Avg	78.0%	80.5%	76.7%	74.3%	72.0%	72.5%	73.8%	71.1%	71.9%			
Score	1	1	1	1	1	1	1	1	1			



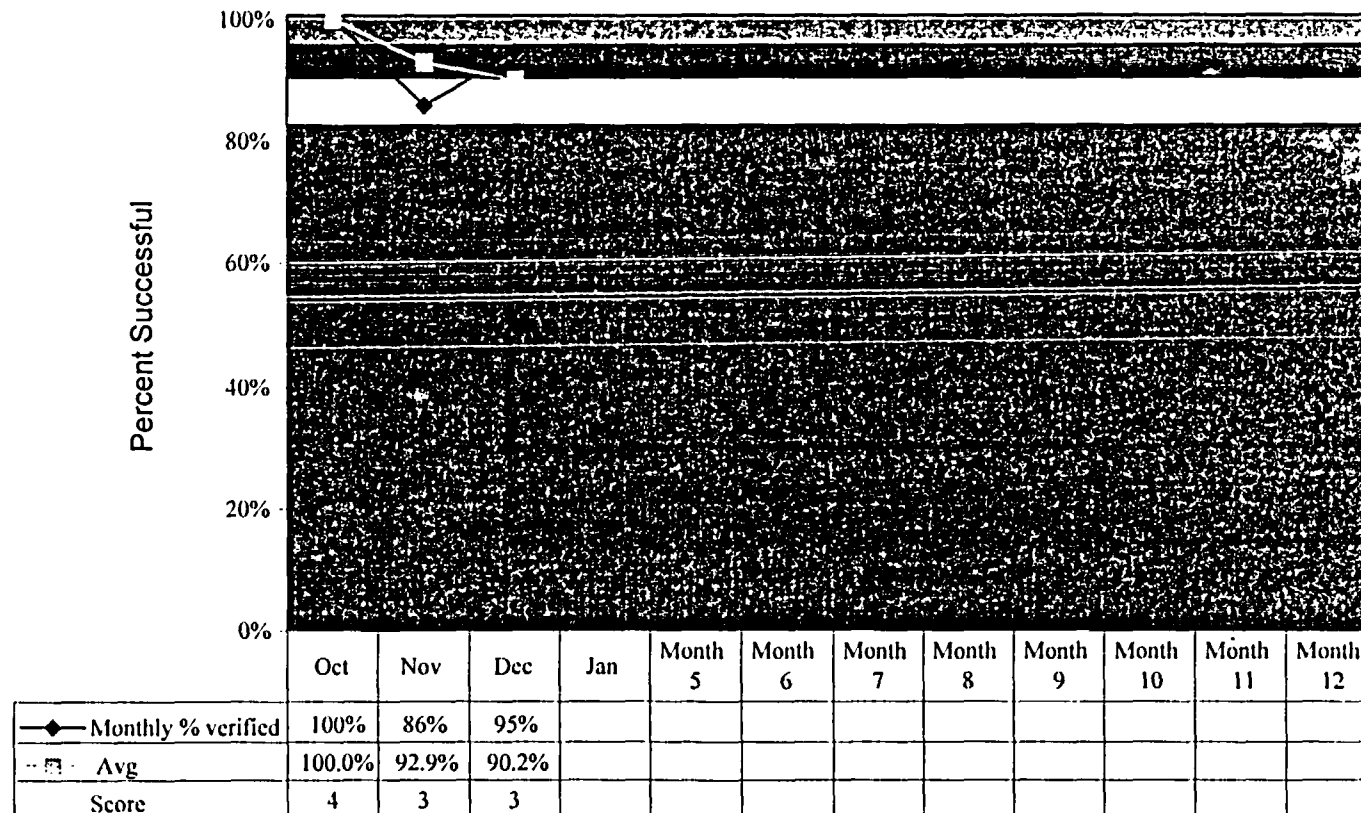
2.3.2.3 Successful Corrective Action Verification

Verify CA were properly implemented.

Score: 3.00



2.3.2 Verification of Quality Performance
2.3.2.3 Successful Corrective Action Verification (.40)
FY 2004



2.3.4 Quality Procedure Process Health

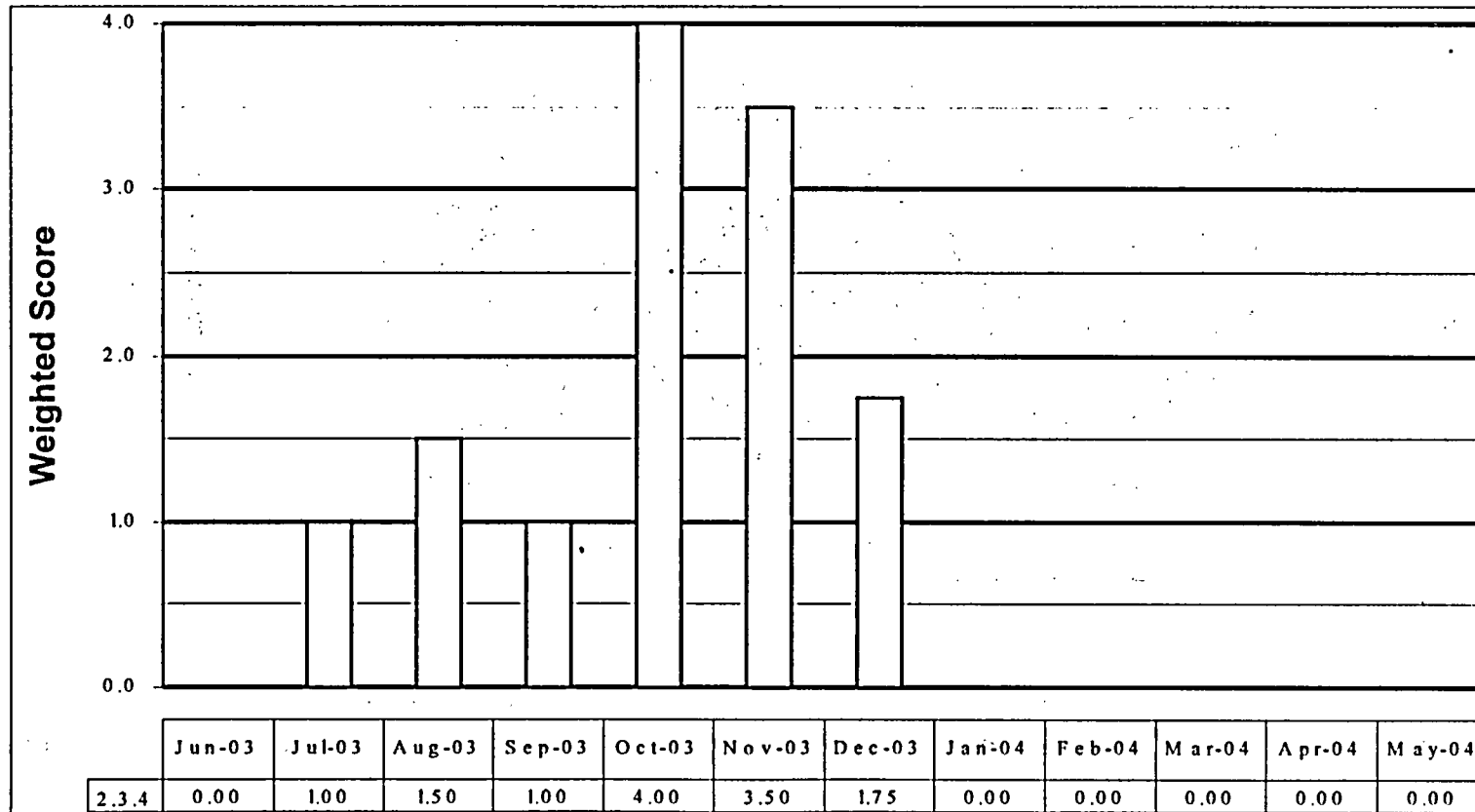
Measure the ability of the Project workforce to develop and follow applicable implementing procedures

Score: 1.75

Y

Contributing Subareas Input

Input	Weight	Value	
2.3.4.1	50	4.00	B
2.3.4.2	50	3.00	C



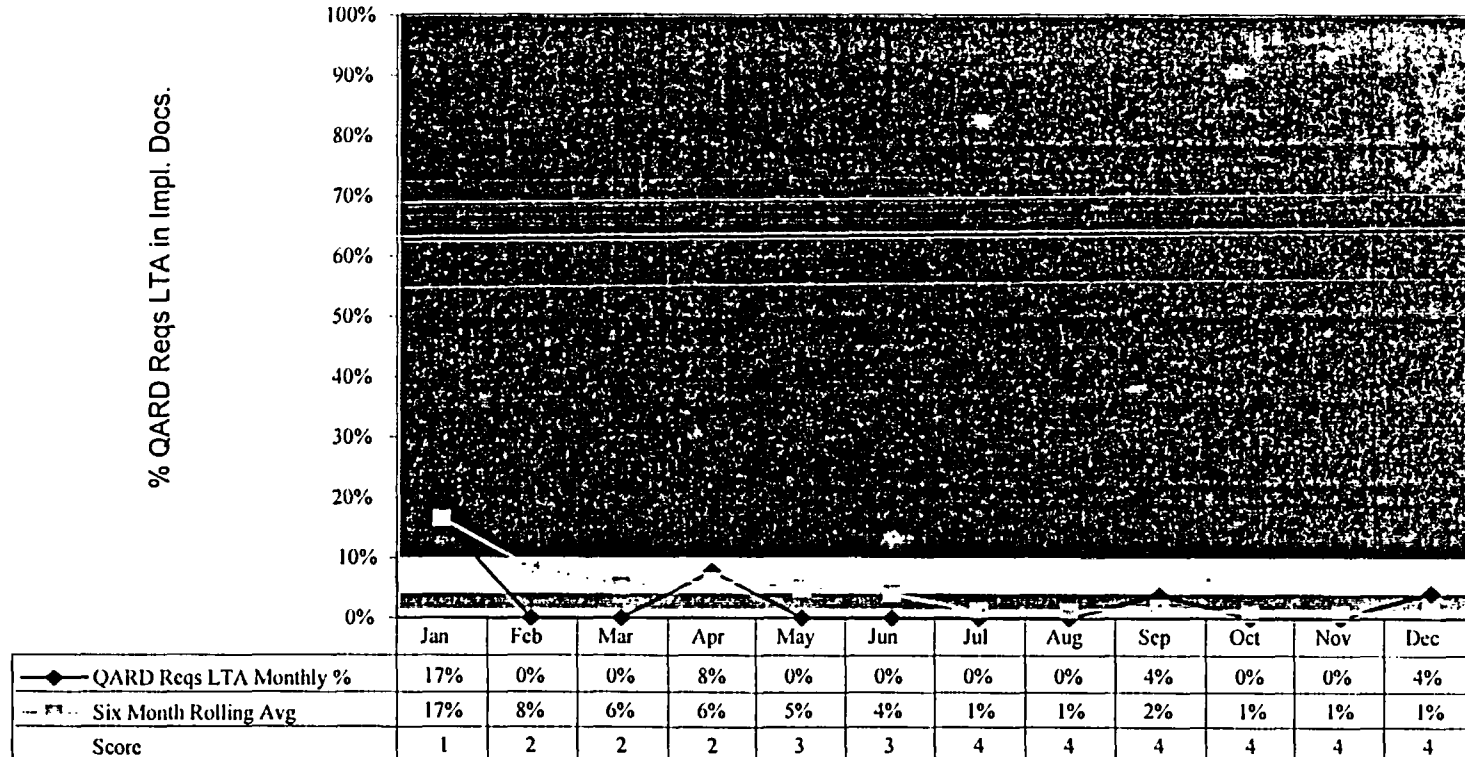
2.3.4.1 Adequacy of QARD Requirements in Implementing Documents

Metric measures QARD requirements missing in project procedures, specifically where the requirement is not flowed down from the QARD to a procedure.

Score: 4.00

B

2.3.4 Quality Procedure Process Health
2.3.4.1 Adequacy of QARD Requirements in Implementing Documents (.25)
Jan - Dec 2003



2.3.4.2 Adequacy of Process in Q level Documentation

Metric measures the adequacy of the procedural process.

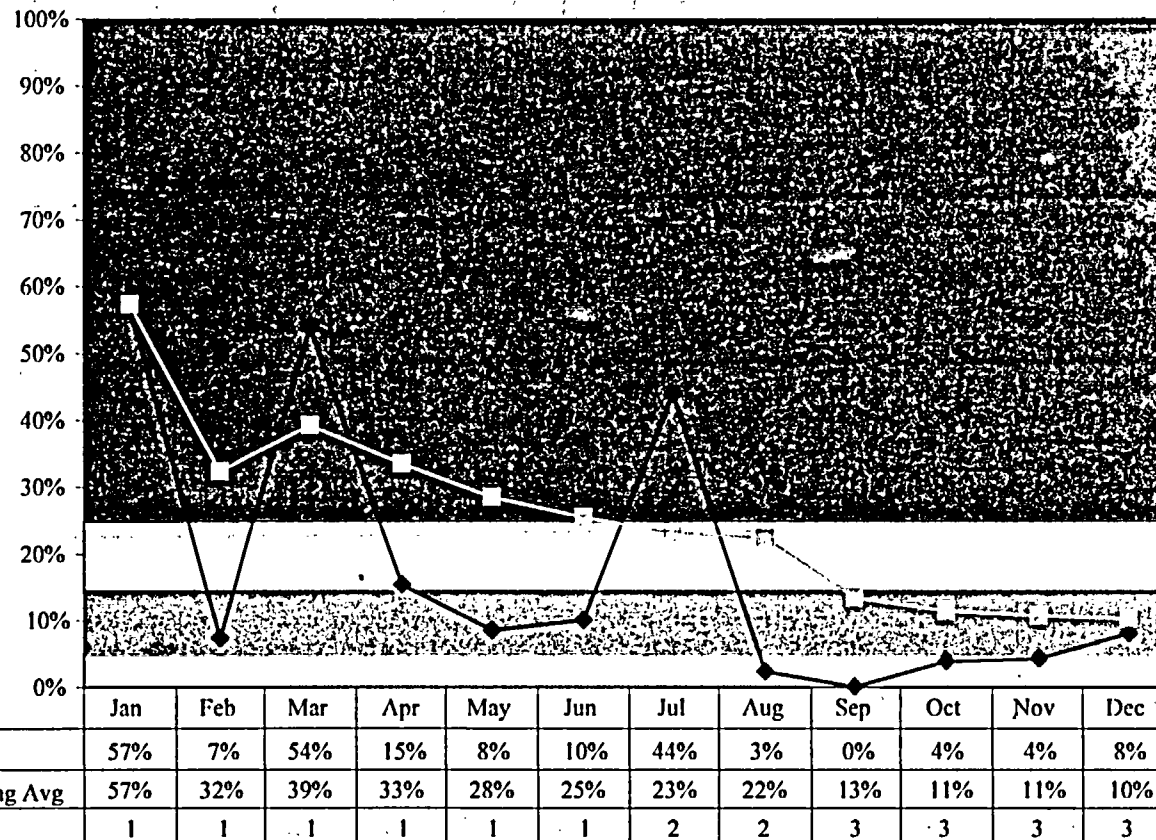
Score: 3.00



2.3.4 Quality Procedure Process Health 2.3.4.2 Adequacy of Process in Q-level Documentation (.25)

Jan - Dec 2003

% Inadequate Process Identified



2.4 Corrective Action Management System

Measurement of workforce effectiveness in utilizing the Corrective Action Management System and management assessments to identify and resolve problems in a timely and efficient manner.

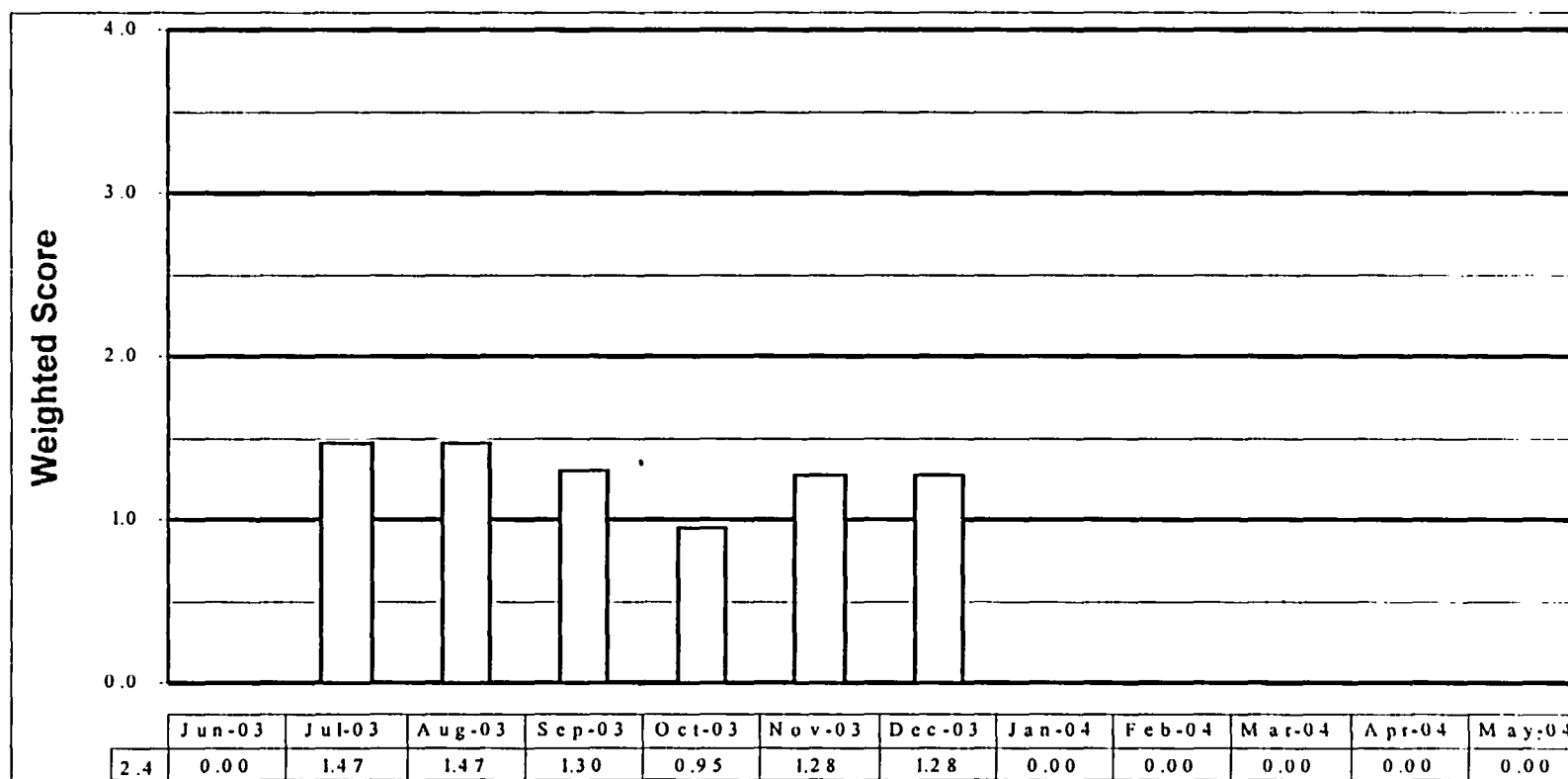
Score: 1.28



Contributing Subareas Input

Input	Weight	Value
2.4.2	20	1.00
2.4.3	25	1.00
2.4.4	55	1.50

R
R
Y



YUCCA MOUNTAIN PROJECT

2.4.2 Self Reporting Culture

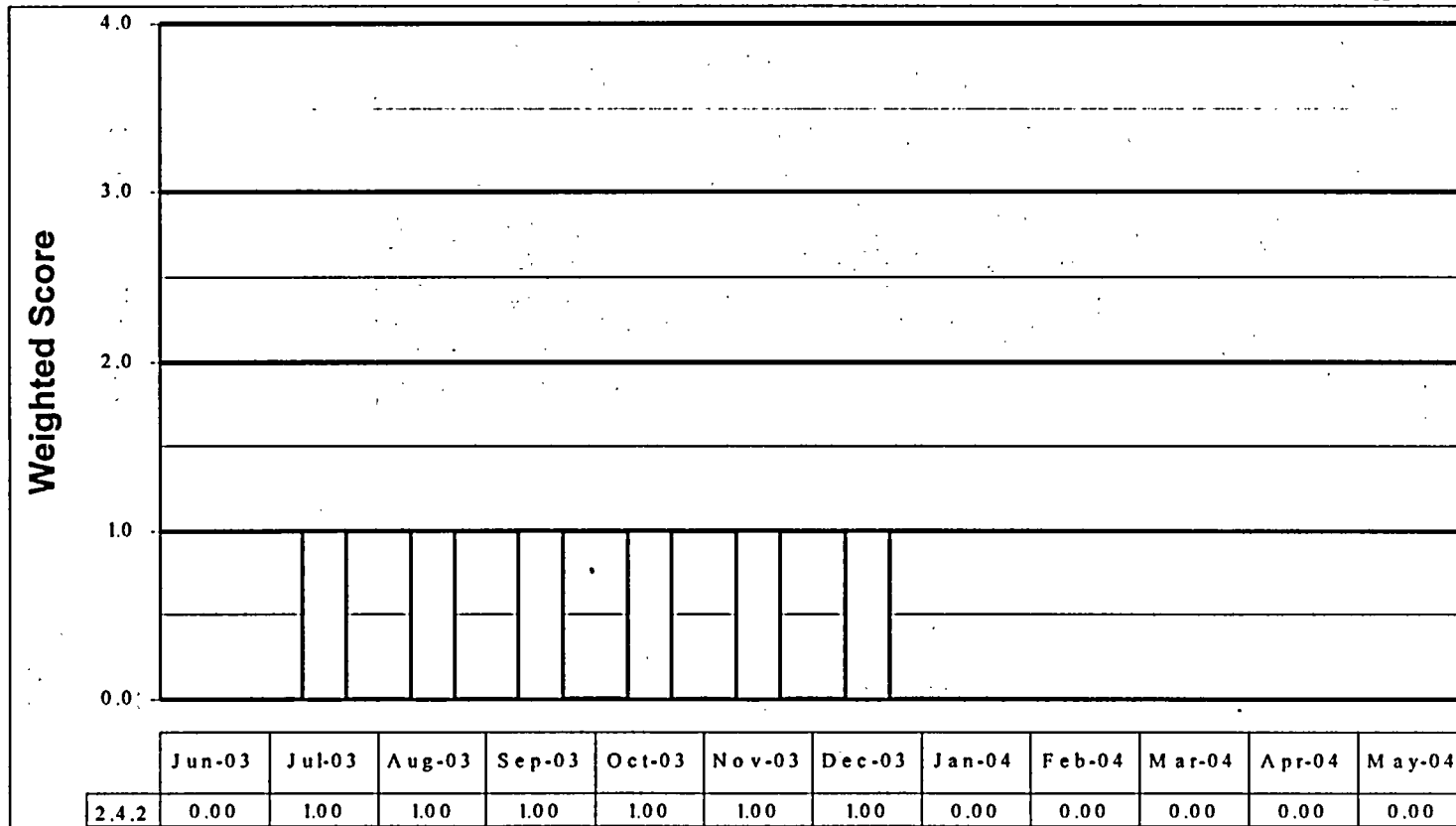
Measurement of the Project workforce's commitment to developing and supporting a self-reporting culture.

Score: 1.00



Contributing Subareas Input

Input	Weight	Value	R
2.4.2.1	50	1.00	R
2.4.2.2	50	1.00	R



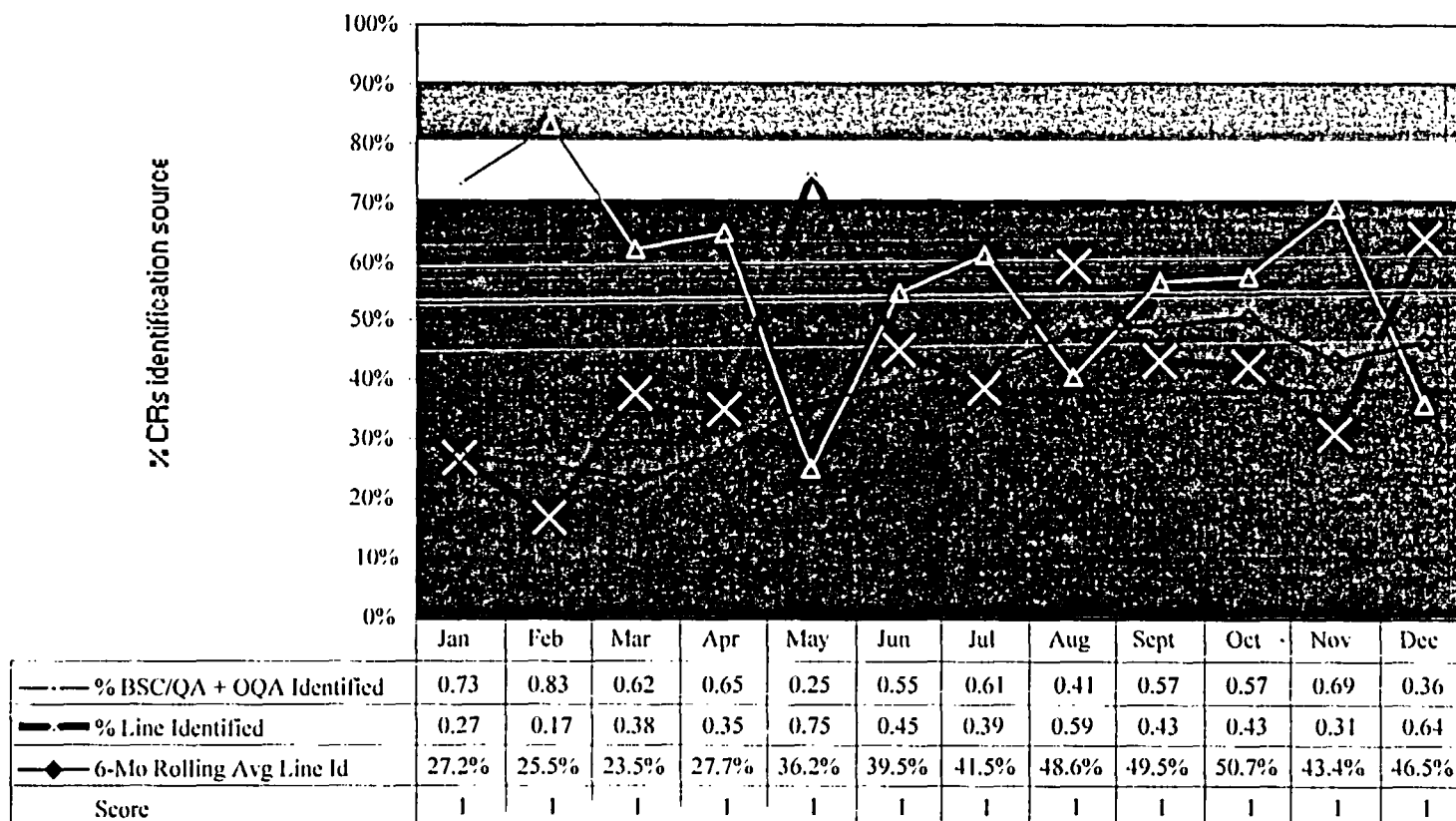
2.4.2.1 Percentage of Adverse Conditions Self-Identified

To measure the overall effectiveness of the self-reporting.

Score: 1.00



2.4.2 Self-Reporting Culture
2.4.2.1 Adverse Conditions (Q-CRs) Self-Identified
Jan - Dec 2003



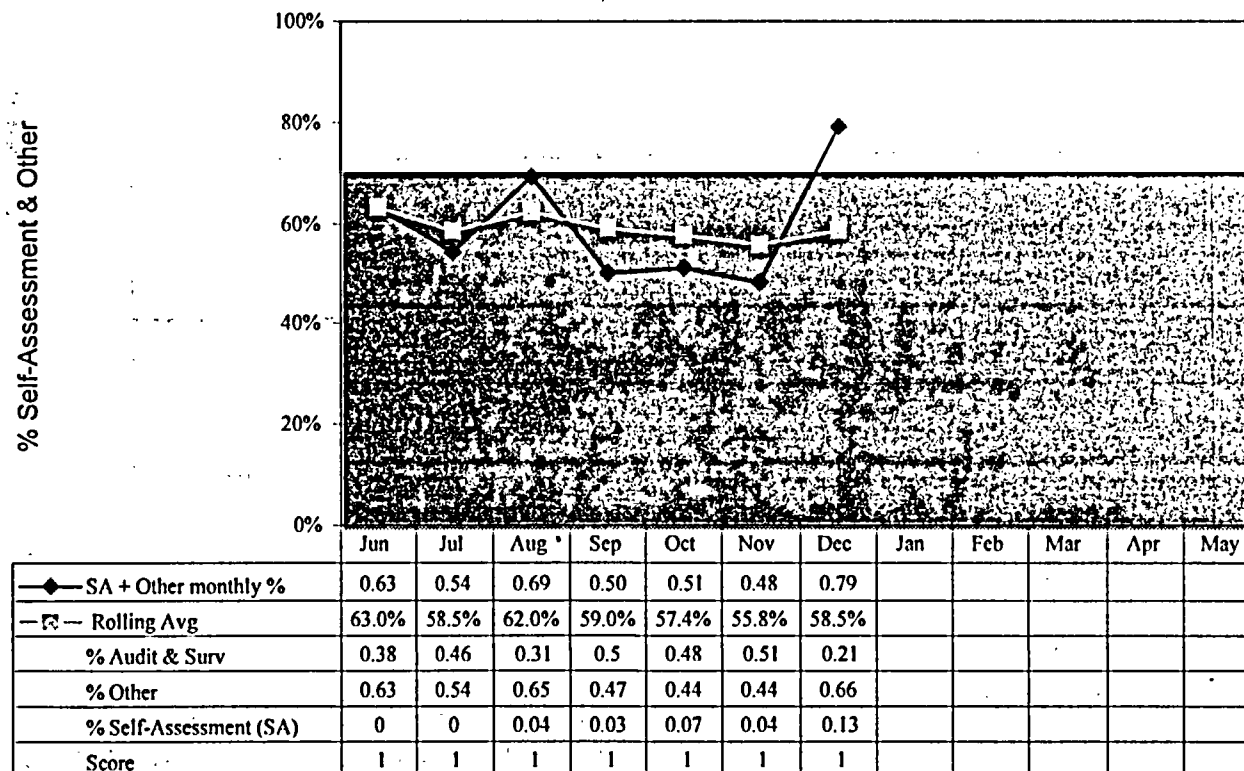
2.4.2.2 Percentage of Adverse Conditions Identified by Process

To measure the effectiveness of the condition reporting culture.

Score: 1.00



2.4.2 Self-Reporting Culture
2.4.2.2 Adverse Conditions Identified by Process
June - Dec 2003



2.4.3 Timely Causal Analysis and Corrective Action Plan Development

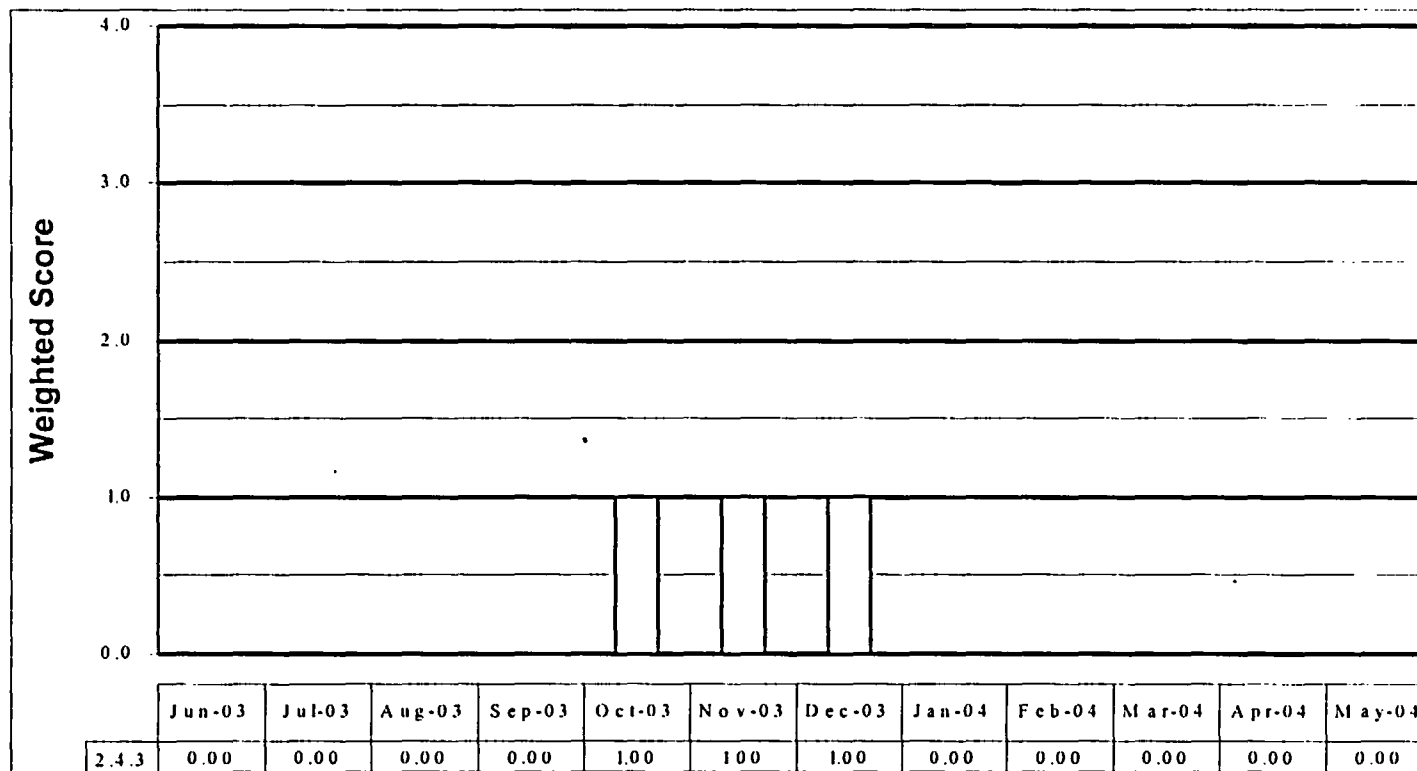
Measurement of the Project's effectiveness in ensuring timely and accurate screening of conditions, preparation of complete analysis, and complete and comprehensive corrective action plans.

Score: 1.00



Contributing Subareas Input

Input	Weight	Value	
2.4.3.1	20	1.00	R
2.4.3.2	70	1.00	R
2.4.3.3	10	1.00	R



2.4.3.1 Timely Screening of New Adverse Conditions

To measure the timely screening of adverse conditions. This metric also is a leading indicator relative to meeting the goal for timely development of corrective action plans.

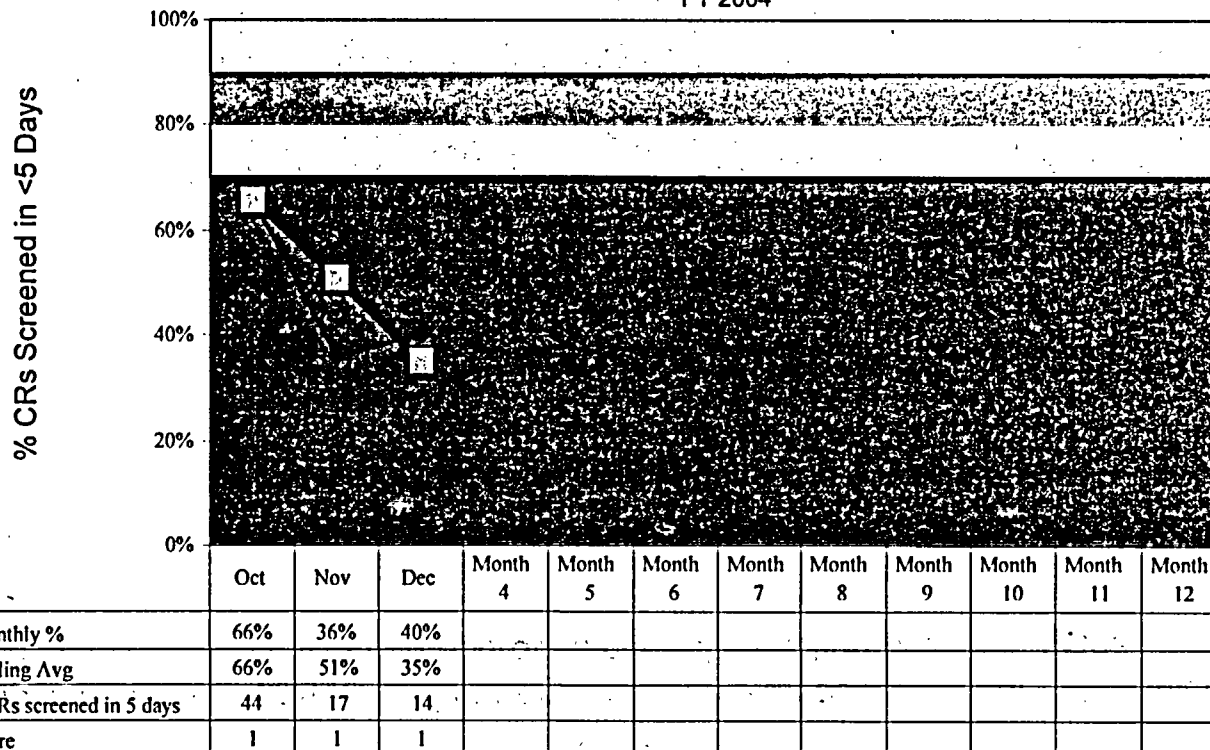
Score: 1.00



2.4.3 Timely Causal Analysis & Corrective Action Plan Development

2.4.3.1 Timely Screening of New CRs (.20)

FY 2004



2.4.3.2 Timely Development of Acceptable Corrective Action Plans

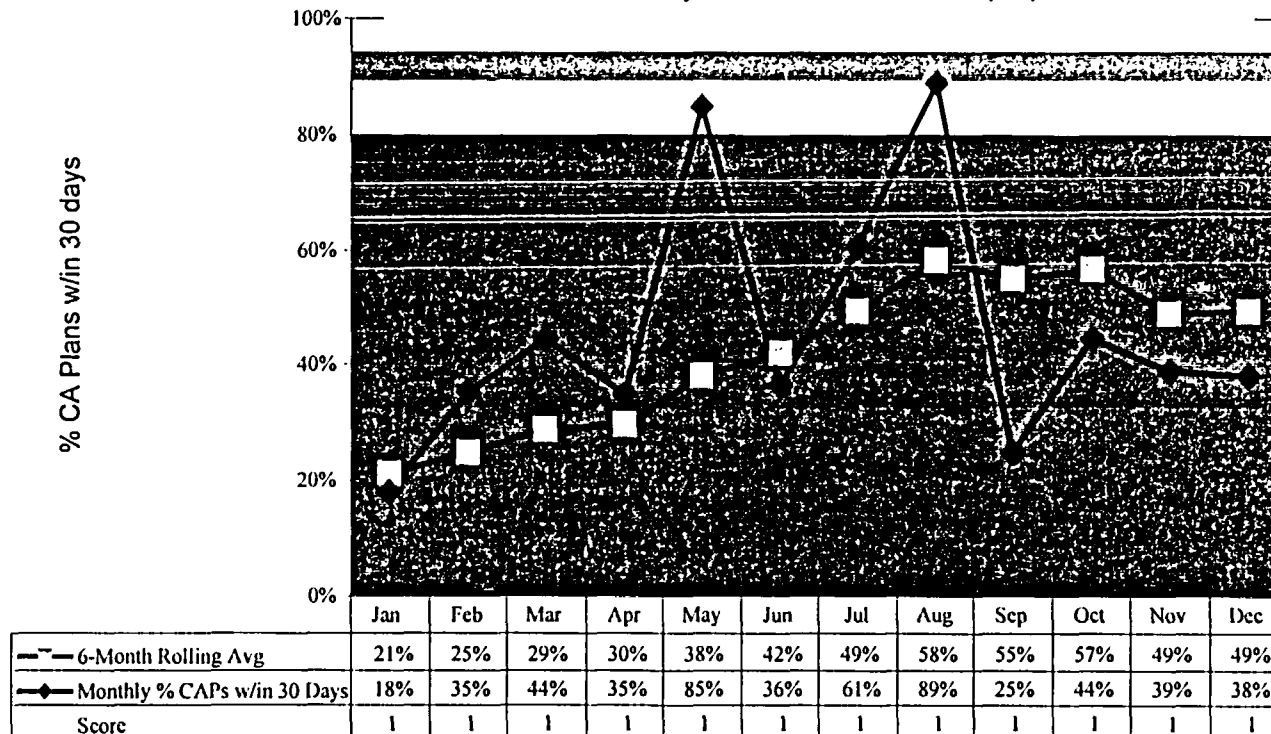
To measure the timeliness of causal analysis and corrective action plan development. The objective is that within 30 days of identification an approved corrective action plan is in place.

Score: 1.00



2.4.3 Timely Causal Analysis and Corrective Action Plan Development

2.4.3.2 Timely Corrective Action Plans (.70)



2.4.3.3 NCR Disposition Timeliness

To measure the timely dispositioning of NCRs so appropriate action can be taken.

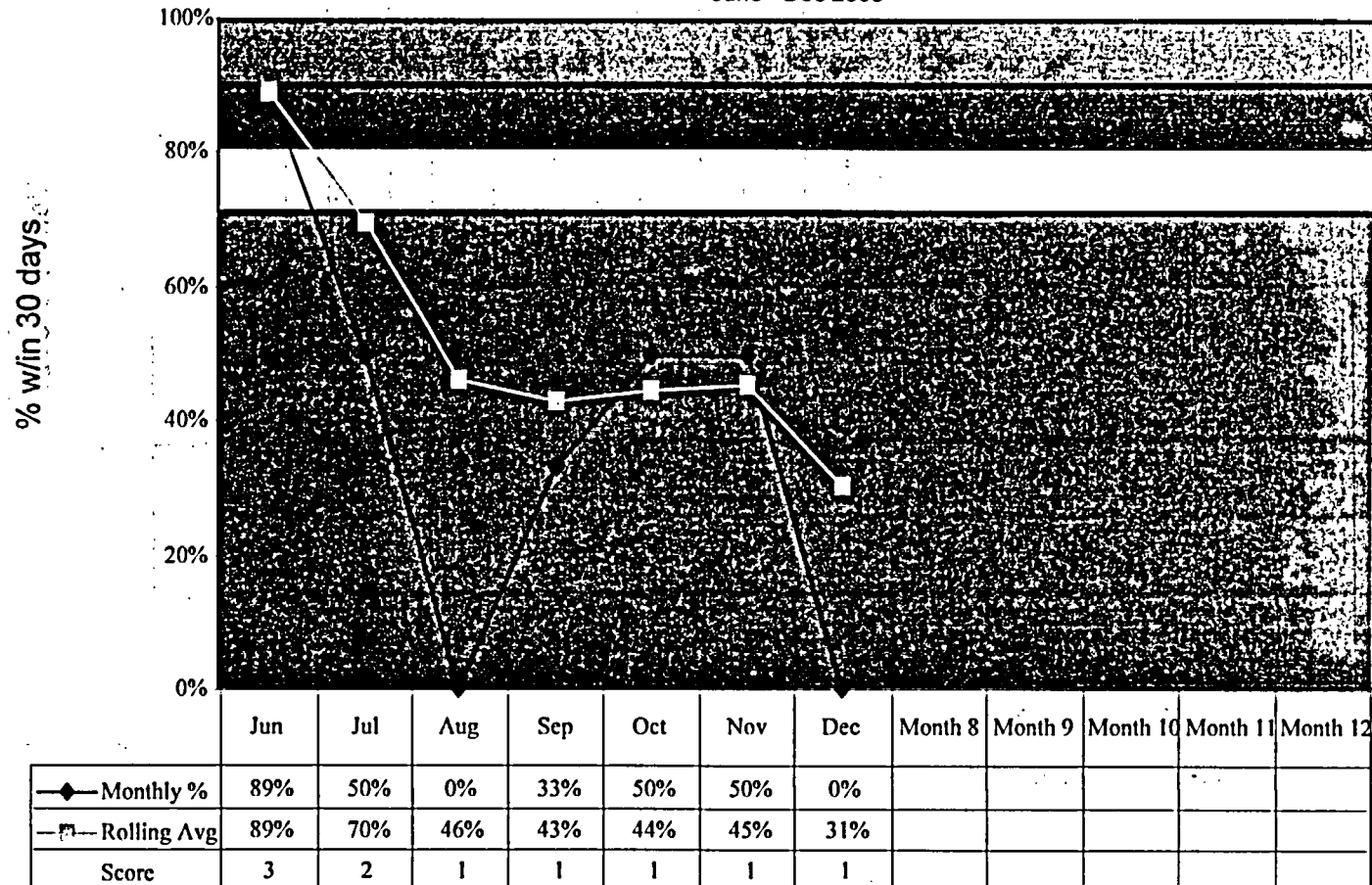
Score: 1.00



2.4.3 Timely Causal Analysis & Corrective Action Plan Development

2.4.3.3 NCR Disposition Timeliness (.10)

June - Dec 2003



2.4.4 Timely Corrective Action and Resolution

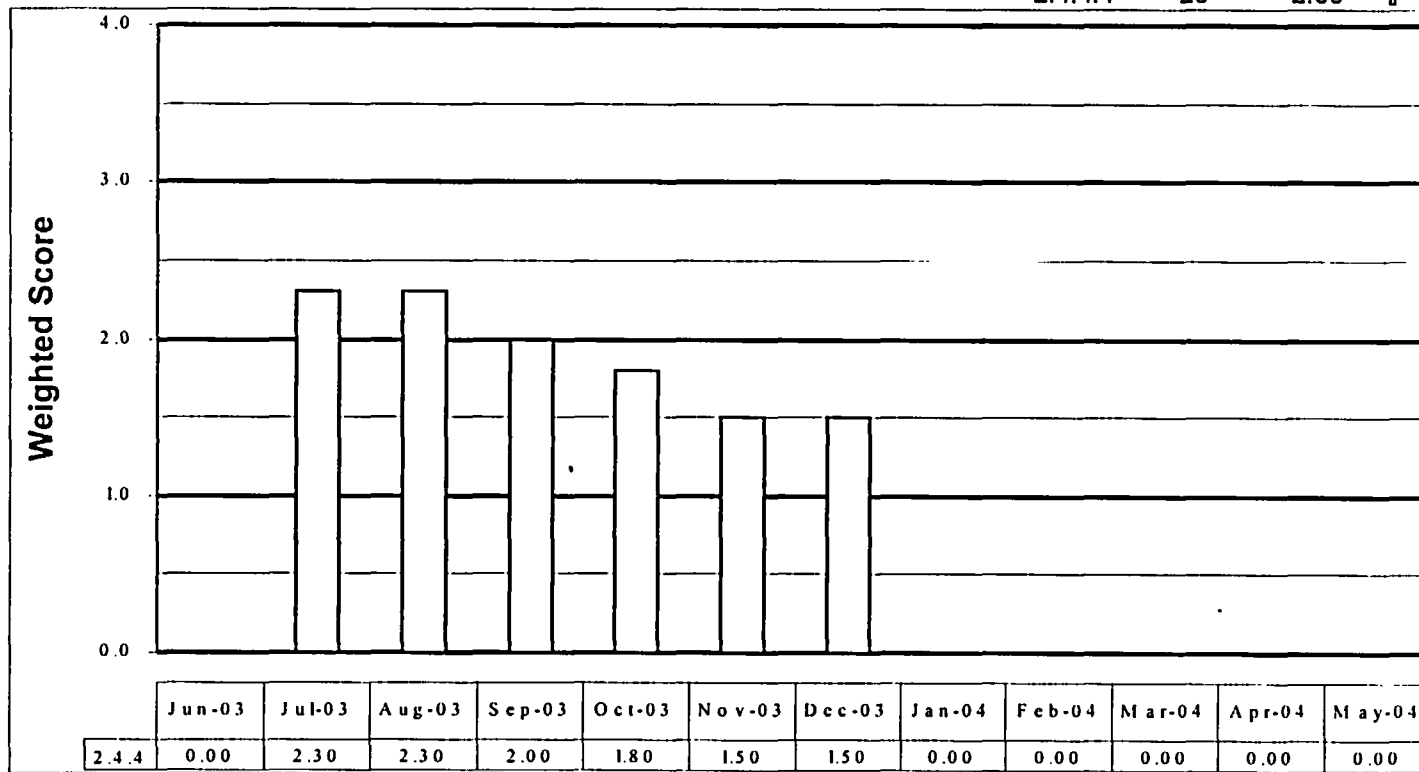
In a well performing organization, adverse/significantly adverse conditions should be corrected within 60/100 days respectively.

Score: 1.50

Y

Contributing Subareas Input

Input	Weight	Value	
2.4.4.1	25	1.00	R R Y Y
2.4.4.2	25	1.00	
2.4.4.3	30	2.00	
2.4.4.4	20	2.00	



2.4.4.1 60-Day Closure of Q Level B CRs

Measures the Project commitment to close 90 percent or more level B Condition Reports within 60 days.
This metric will also track the number of Q level B CRs remaining open at the end of each month.

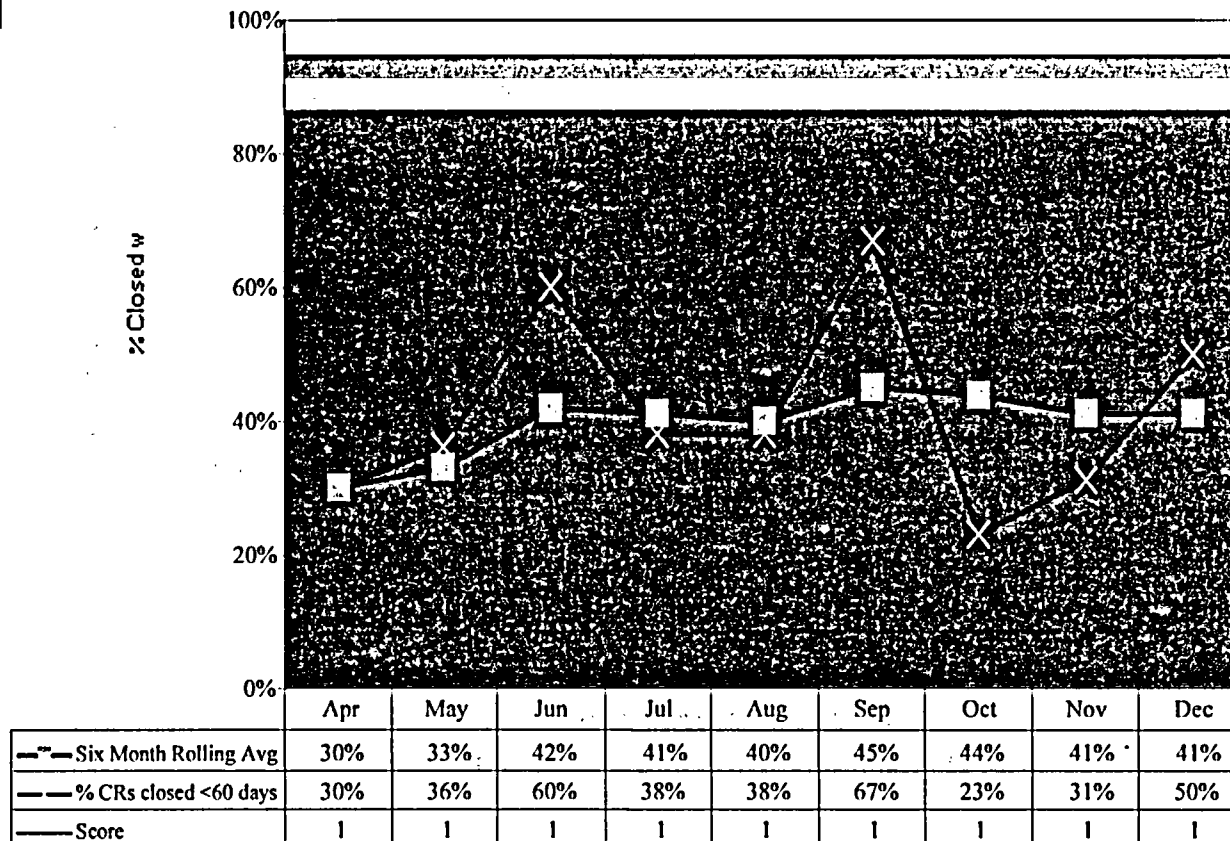
Score: 1.00



2.4.4 Timely Corrective Action and Resolution

60-Day Closure of Q Level B CRs (.25)

Jan - Dec 2003



2.4.4.2 100-Day Closure of Q Level A CRs

Measures the Project commitment to close 90 percent or more level A Condition Reports within 100 days.
This metric will also track the number of level A CRs remaining open at the end of each month.

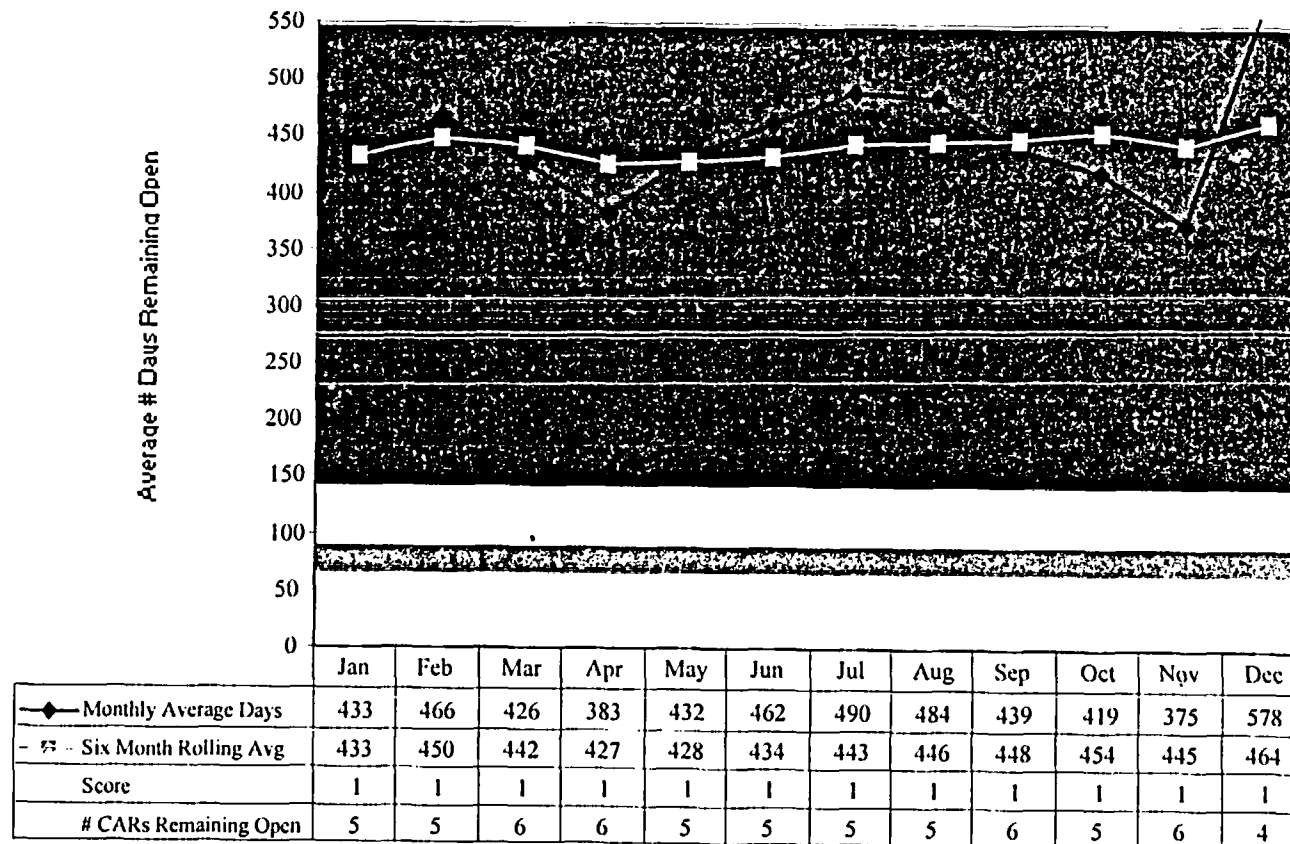
Score: 1.00



2.4.4 Timely Corrective Action & Resolution

100-Day Closure of Q Level A CRs (CARs) (.25)

Jan - Dec 2003



2.4.4.3 Condition Report Action Implementation Timeliness

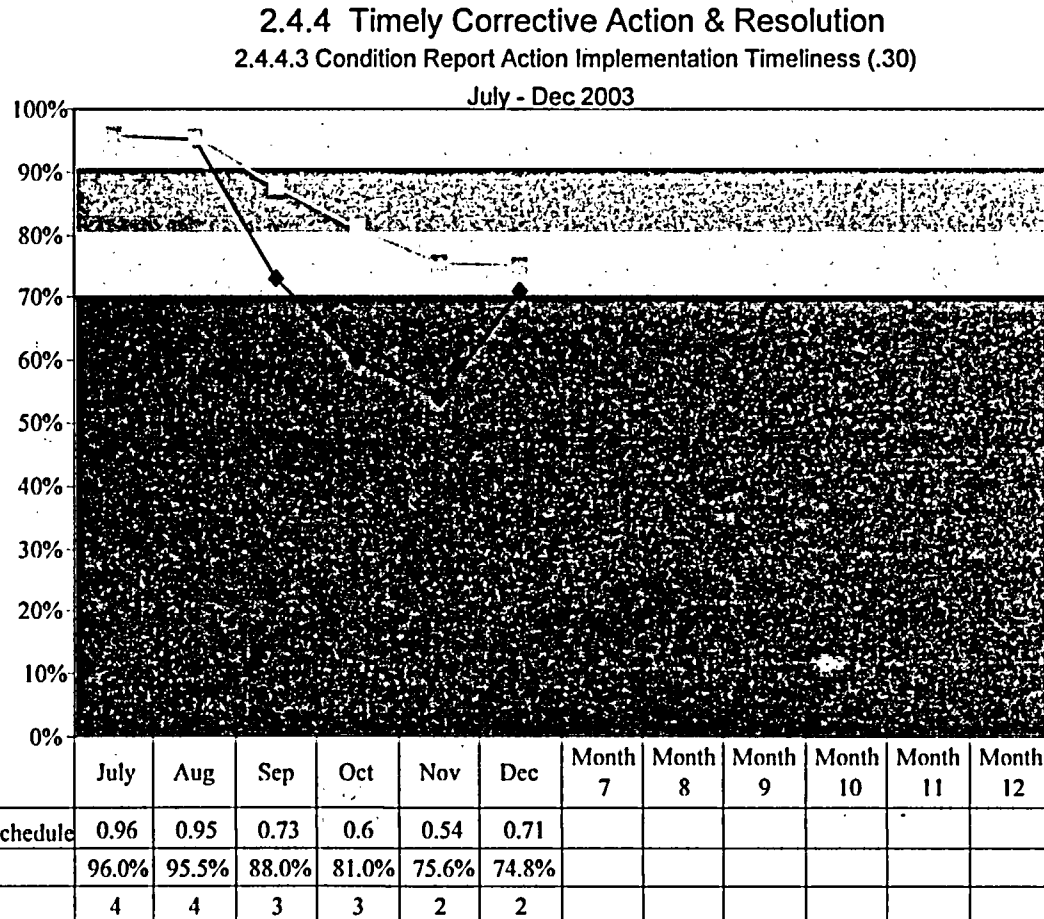
This indicator measures the organizations ability to complete individual actions in a timely manner.

Score: 2.00



Percent Actions On Sched

Percent Actions on Schedule



2.4.4.4 Corrective Action System Activity Ratio

To measure issues opened each month as compared to issues closed during same period.

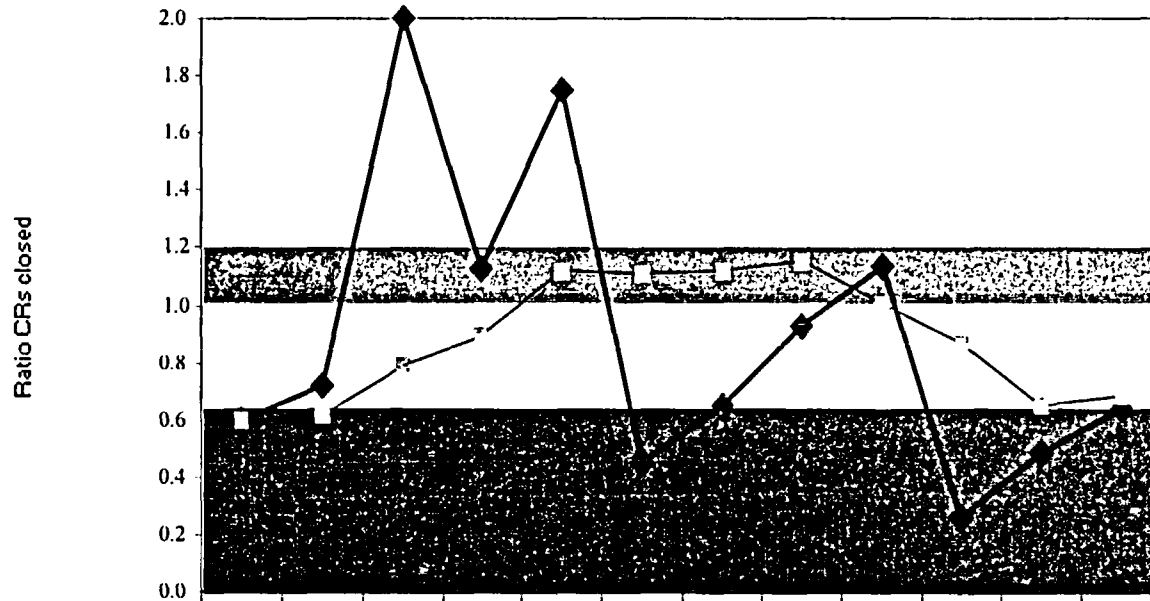
Score: 2.00



2.4.4 Timely Corrective Action & Resolution

2.4.4.4 Corrective Action System Activity Ratio (.20)

Jan - Dec 2003



	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Ratio closed versus open	0.6	0.7	2.0	1.1	1.8	0.5	0.7	0.9	1.1	0.3	0.5	0.6
Six Month Rolling Avg	0.6	0.6	0.8	0.9	1.1	1.1	1.1	1.2	1.0	0.9	0.7	0.7
# Issues closed	9	13	16	18	21	5	13	24	34	14	22	30
# Issues opened	15	18	8	16	12	11	20	26	30	54	45	47
Score	1	1	2	2	3	3	3	3	3	2	2	2





U.S. Department of Energy
Office of Civilian Radioactive Waste Management



Trending Program Improvements

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Michael Mason
Manager, Quality Assurance
Bechtel SAIC Company LLC

February 2004

CONFIDENTIAL

Trend Evaluation and Reporting

- **Requirements and Industry Best Practices**
- **Process Improvements**
- **Trends and Patterns Analysis**
- **Results and Findings**
- **Summary**
- **Acting on the Results**



Requirements and Industry Best Practices

- **Quality Assurance Requirements Description (QARD) Requirements**
 - Conditions adverse to quality shall be evaluated to identify adverse quality trends and help identify root causes
 - Performed in a manner and at a frequency that provides for prompt identification of adverse quality trends
- **Industry Best Practices**
 - Institute of Nuclear Power Operations (INPO) - Information in performance reporting/corrective action systems is periodically assessed for trends
- **Performance Objective**
 - Provide line management with information relative to potentially identifying recurring problems and systemic or programmatic causes (common causes)



Trending Process Improvements

- **AP-16.3Q, *Trend Evaluation and Reporting* revised, effective September 30, 2003**
- **Process changed to focus on trend evaluation and analysis through resolution**
 - Uniform cause codes and training on cause analysis implemented
 - Reporting frequency increased to quarterly
 - New criteria and process for identifying repetitive problems and trends
 - ♦ Statistical and Qualitative Criteria
 - ♦ Common Cause Analysis
 - Adverse and emerging trends documented in corrective action system to track associated actions



Trending Process Improvements

(Continued)

- **AP-16.4Q, *Causal Analysis and Corrective Action Plan Development* revised, effective September 29, 2003**
 - Process changed to reflect industry best practice (Root Cause Analysis INPO-OE-907)
 - Integrates the causal analysis and corrective action development activities into one process
 - Validation criteria on causal factors and corrective actions
 - Human performance and error precursor concepts from INPO integrated into the process
 - ♦ Skill, rule, and knowledge based errors
 - New training for evaluators and root cause analysts developed and provided



Trending Process

- **Data collection and analysis**
 - **Condition reports are identified and data extracted**
 - ♦ **Process/Procedure**
 - ♦ **Owner/Organization**
 - ♦ **Cause(s)**
 - ♦ **Corrective actions**
 - **Data is reviewed for completeness and accuracy**
 - **Data is then sorted and evaluated for trends and patterns by a team**
 - ♦ **Trends and Patterns Analysis helps to identify likely areas (outliers) to focus on identification of common causes and ineffective corrective action**
 - ♦ **Pareto charts and statistical techniques used to identify outliers**



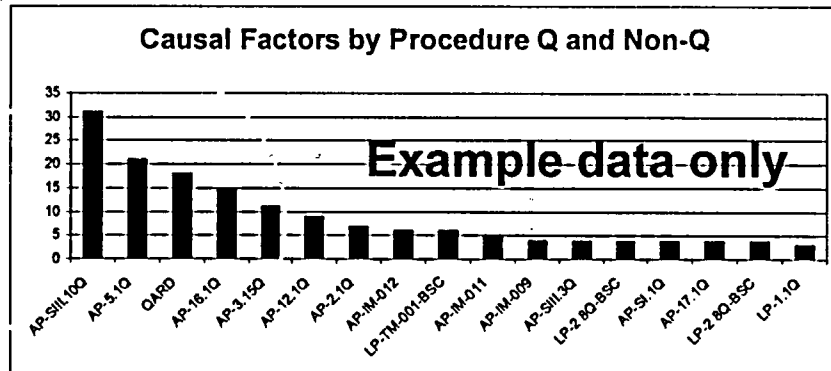
Trends and Patterns Analysis

Example Data Only

	Procedure or Process				
Causal Factor	AP-1.XX	AP-2.XX	AP-3.XX	AP-4.XX	Total
Design/Engineering	2	3	2	4	11
Equipment/Material	1	0	0	1	2
Human Performance	10	15	13	10	48
Management	2	1	8	1	12
Communications	5	15	12	15	47
Training	1	2	5	2	10
Total	21	36	40	33	

**Common Cause
Analysis**

**Recurrence/
Repetitive Problems**



Trending Process

(Continued)

- Once a trend or pattern is observed, the Condition Reports (CRs) that contributed to the trend or pattern are read and evaluated for:
 - Risk significance or impact
 - Error-prone process or single failure points
 - Recurring problems



Trend Evaluation Results/Findings

- **Issued 4th Quarter FY03 Trend Evaluation Report using the new process and techniques**
 - **Able to identify the processes that are experiencing the most errors in implementation**
 - **Able to identify why those processes have errors**
 - **Able to take focused corrective action based on the error likely situations and the associated causes**
 - **Able to focus on the specifics**



Trend Evaluation Results/Findings

(Continued)

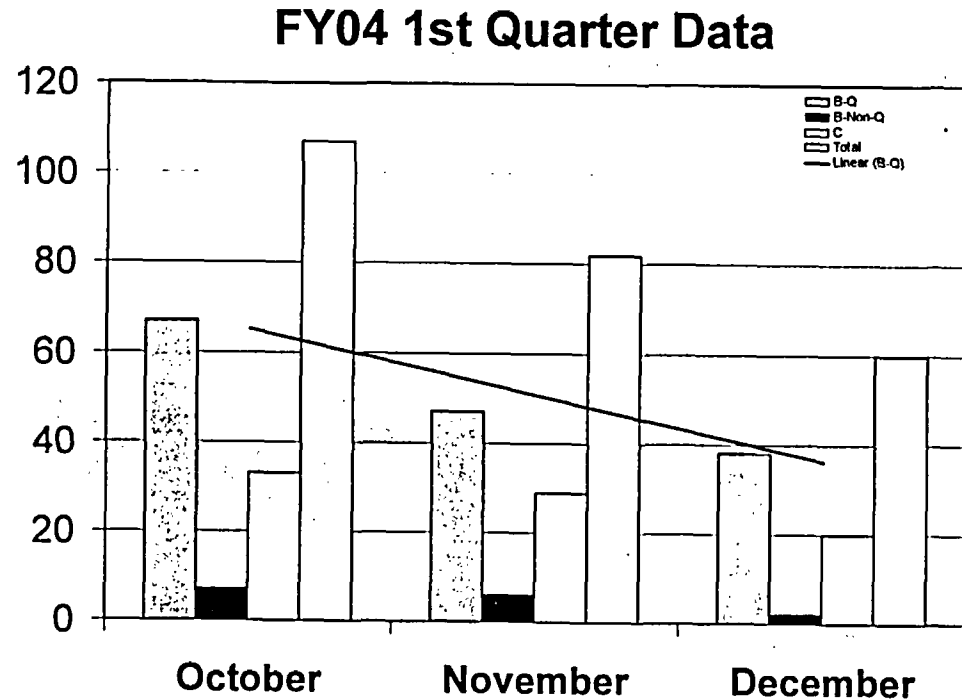
- **Recent results for 1st Quarter FY04**
 - Six procedures account for over half of our problems
 - The most common cause is human performance in implementation
 - Content (requirements) of the procedures is not a problem
 - Problems primarily related to documentation errors
 - Excessive pace (schedule over quality) identified in only 1.3 percent causal factors



Trend Results Overall

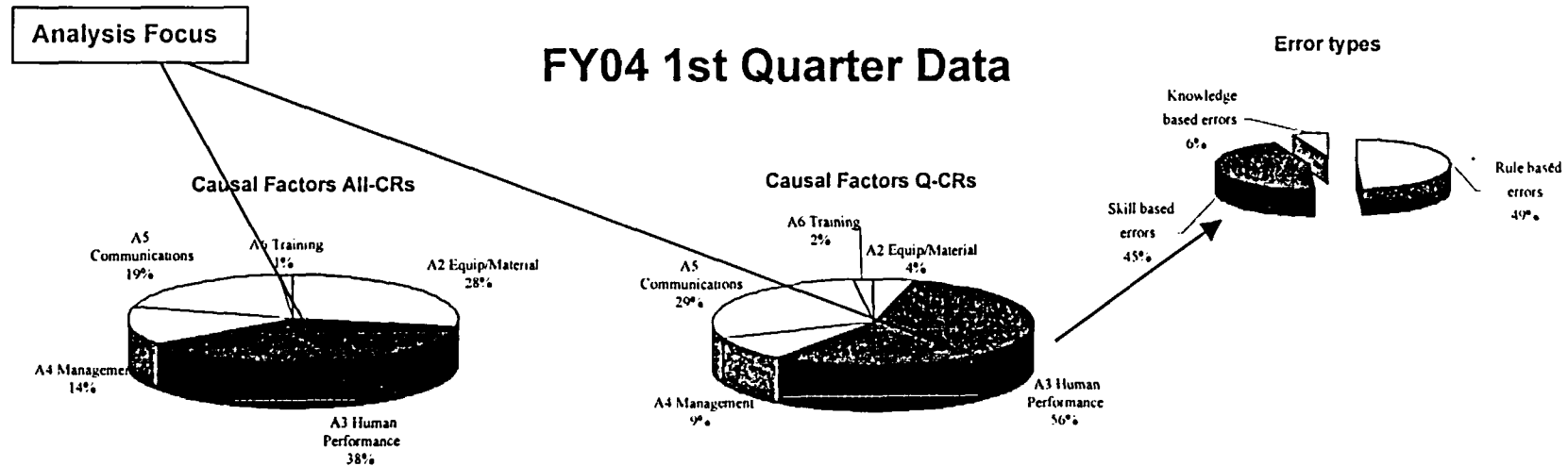
- **Analysis results**

- Statistically significant trend is the result of process variation (influence of holiday periods)
- A review over the previous 12 months indicates peaks occur relative to audit activity



Trend Results Overall

(Continued)



- **Analysis results**

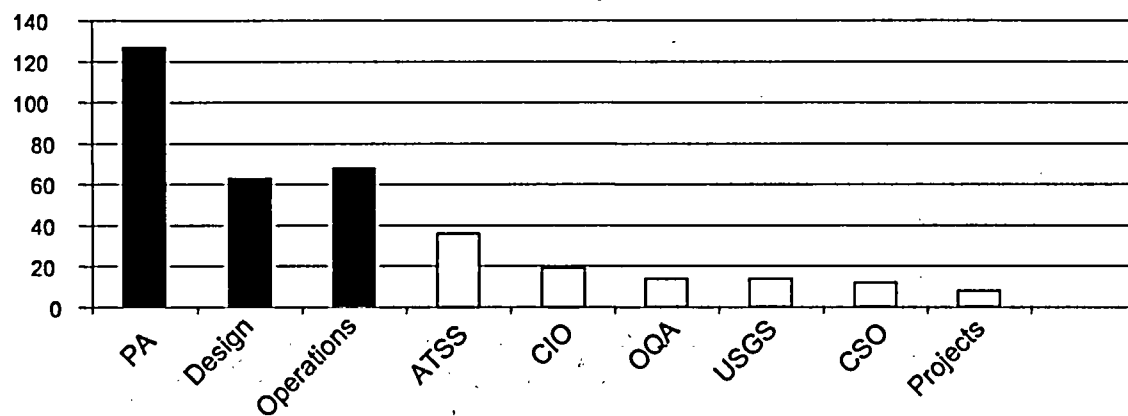
- Equipment causal factors are influenced by Non-Q NCR activity
- Human performance causal factors are influenced by skill and rule based errors



Trends Results by Organization

Calendar 03 Data

Causal Factors by Organization



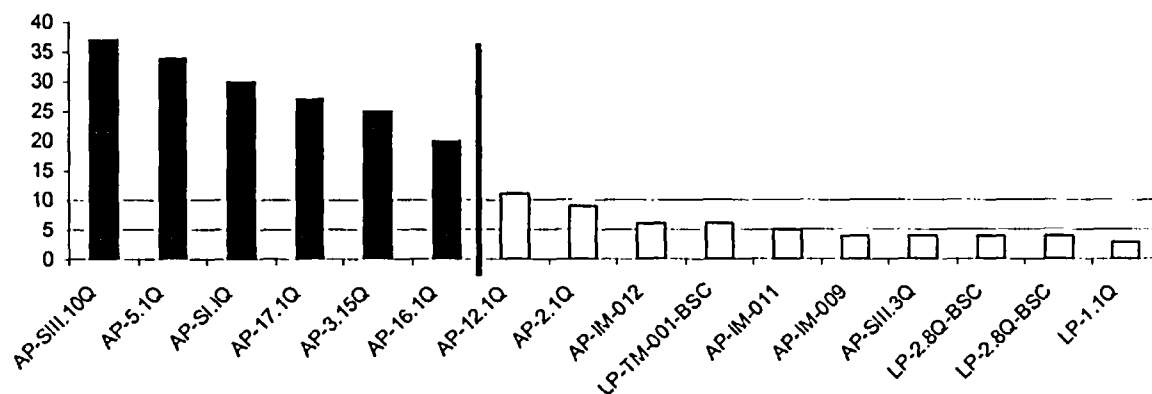
Organization	Principal Cause Category					
	A1 Design Engineering	A2 Equipment/ Material	A3 Human Performance	A4 Management	A5 Communications	A6 Training
Performance Assessment (PA)	0	5	58	25	31	0
Repository Design (Design)	4	1	10	4	8	0
Site Operations (Operations)	2	3	10	7	9	1



Trends Results by Process

Calendar 03 Data

Causal Factors by Procedure Q and Non-Q

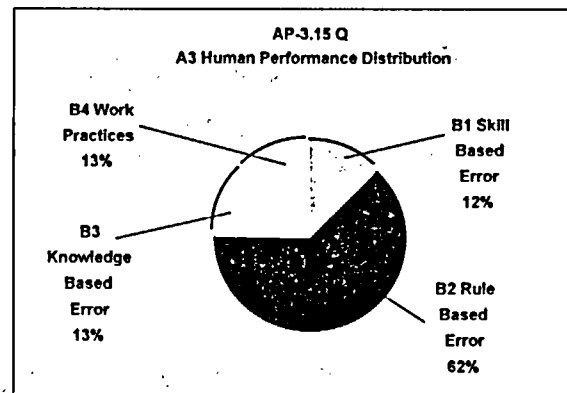
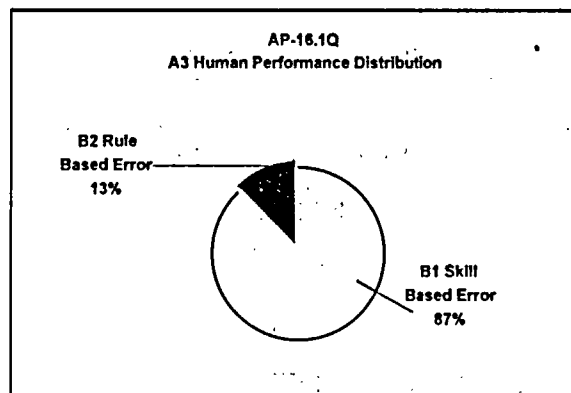
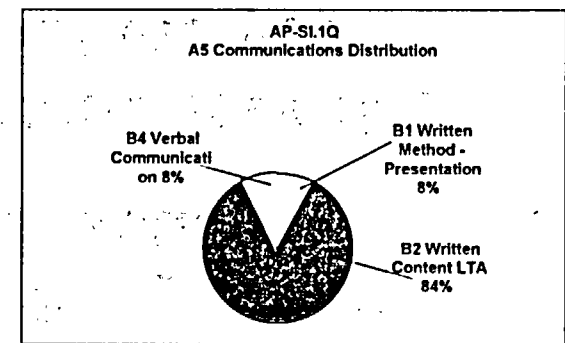
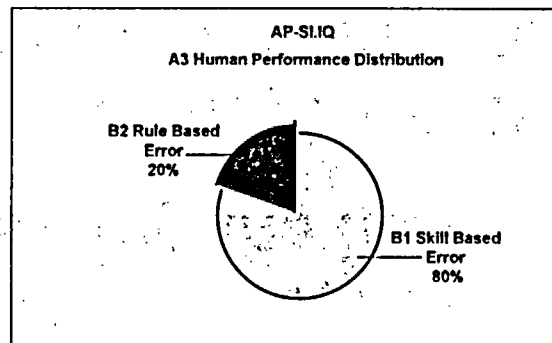
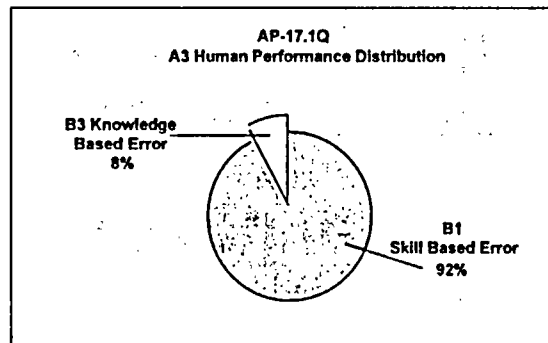
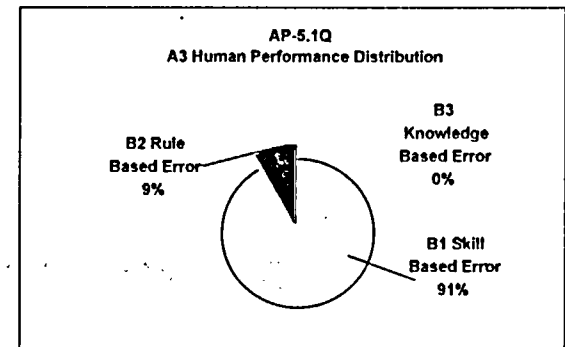
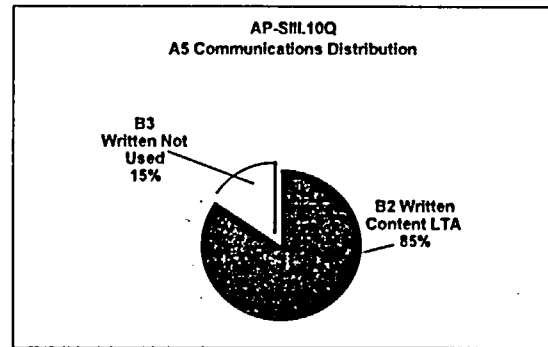
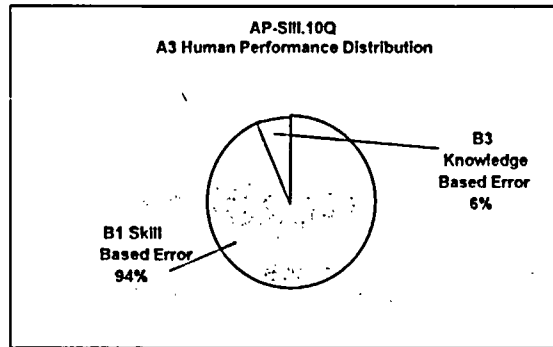


Procedure	Principal Cause Category					
	A1 Design Engineering	A2 Equipment/ Material	A3 Human Performance	A4 Management	A5 Communications	A6 Training
AP-SIII.10Q Models	0	0	17	7	13	0
AP-5.1Q Procedure Preparation, Review, and Approval	0	0	23	2	6	1
AP-SI.1Q Software Management	0	0	10	5	14	1
AP-17.1Q Records Management	0	0	13	9	5	0
AP-3.15Q Managing Technical Product Inputs	0	0	13	5	7	0
AP-16.1Q Condition Reporting and Resolution	0	0	16	0	4	1



Trends Results by Process

(Continued)



Trend Results Summary

- **As a result of audit activities, different procedures are accounting for our problems quarter-to-quarter**
- **Problem areas were expected and management is proactively addressing the identified issues**
- **Processes are in control given the amount of data and work being conducted throughout the year**
- **We now understand the nature and causes of problems with these processes**



Acting on the Results/Findings

- **Issued CR-1497 to address the 4th Quarter FY03 Trend Evaluation Report recommendations**
 - **Corrective Action Plan has been developed to address the trend report findings**
 - **CR Plan Summary:**
 - ♦ **Implement an event/error prevention framework based on INPO and commercial nuclear practices to address human performance errors in procedure implementation**





U.S. Department of Energy
Office of Civilian Radioactive Waste Management



Quality Assurance Requirements and Description

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Michael L. Ulshafer
Team Lead, Office of Quality Assurance
Office of Civilian Radioactive Waste Management
U.S. Department of Energy

Yucca Mountain
Radioactive Waste Management

Quality Assurance Requirements and Description

- **Quality Assurance Requirements and Description (QARD), Rev. 13, currently under revision**
 - **Draft Rev. 14 addresses:**
 - ♦ **Allowance for line ownership of the Corrective Action Program (Sections 15, 16, and 18)**
 - ♦ **Inadvertent placement of an “and” instead of an “or” when utilizing Peer Review/Independent Technical Reviews (Supplement III)**
 - ♦ **Delete all system, structures, and components (SSCs) that are not classified as “important to safety” or “barriers important to waste isolation” from the QARD (Section 2.0)**



Quality Assurance Requirements and Description

(Continued)

- Draft Rev. 14 Status**
 - ♦ Next draft has been prepared and reviewed internally by the Office of Quality Assurance (OQA) and addresses:**
 - » 10 CFR 63, Subpart G, Quality Assurance**
 - » NUREG 1804, Yucca Mountain Review Plan**
- Requirement matrices formatted to facilitate review**
 - ♦ Full text requirements to QARD**



Quality Assurance Requirements and Description

(Continued)

- **Path Forward for QARD that implements the requirements of 10 CFR 63, Subpart G:**
 - **Formal review/comment cycle - 2nd Quarter FY04**
 - **Resolve comments - 3rd Quarter FY04**
 - **Technical Exchange or Appendix 7 meeting with NRC - 3rd or 4th Quarter FY04**
 - **Approval by DOE - 4th Quarter FY04**
 - **Review/approval by NRC - 4th Quarter FY04**
 - **Effective Date - 1st Quarter FY05**





U.S. Department of Energy
Office of Civilian Radioactive Waste Management



Model Validation Status for Condition Report 99 (CAR BSC-01-C-001)

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Jean Younker
Chief Science Officer
Bechtel SAIC Company, LLC

Belmont, MA
November 15, 2001

Model Development and Validation Condition Report 99 Background

- **Condition Report (CR) CR 99/BSC-01-C-001 issued May 2001**
 - **Corrective Actions (CAs) included changes to address model validation issues identified in technical products, procedure enhancements, and extensive training**
- **BSC completed CAs and requested DOE/Office of Quality Assurance (OQA) verification August 2003**



Model Development and Validation Condition Report 99 Background

(Continued)

- **Comprehensive Model Audit was conducted by DOE/OQA October 2003**
 - **Timing corresponded with availability of Model Reports for review**
 - **Audit Findings**
 - ♦ **Procedure found adequate**
 - ♦ **Problems with implementation**



Model Development and Validation Condition Report 99 Background

(Continued)

- **August-November 2003, DOE/OQA verified 11 of the 12 CR 99 CAs were complete**
 - DOE/OQA Verification Team selected 20 Model Reports for independent technical review
 - 6 of 20 Model Reports sampled were “Unsatisfactory”
 - ♦ One Model Report was corrected during the verification review
- **On November 18, 2003, DOE/OQA concluded CR 99 could not be closed**



Condition Report 99 Supplemental Corrective Actions

- **BSC submitted 3 supplemental corrective actions
December 5, 2003**
 - Self-Assessment to investigate procedural implementation problems
 - Surveillance of remaining Model Reports
 - Address issues with 5 “unsatisfactory” Model Reports
- **DOE Line and OQA approved these supplemental
actions December 10, 2003**



Condition Report 99 Supplemental Corrective Actions

(Continued)

- **Action #1: Conduct Self-Assessment**
 - Completed January 15, 2004
 - No Level B CRs identified
 - Two Opportunities for Improvement entered into the Corrective Action Program (CAP)
- **Action #2: Surveillance of 36 additional Model Reports**
 - Technical specialists on BSC Surveillance Team are completing model validation checklists
 - Surveillance Report on schedule for completion February 20, 2004
 - Initial results suggest frequency and type of findings will be similar to DOE/OQA independent review of 20 Model Reports



Condition Report 99 Supplemental Corrective Actions

(Continued)

- **Action #3: Revise 5 Model Reports judged as “Unsatisfactory” by DOE/OQA Verification Review Team**
 - **4 Model Reports revised and approved by BSC**
 - ♦ **Calibration of Site Scale Flow Model: Approved December 17, 2003**
 - ♦ **Radionuclide Transport Models Under Ambient Conditions: Approved December 13, 2003**
 - ♦ **Analysis of Waste Package and Drip Shield Degradation: Approved December 5, 2003**
 - ♦ **Atmospheric Dispersal and Deposition of Tephra from a Potential Volcanic Eruption at Yucca Mountain, Nevada: Approved February 9, 2004**



Condition Report 99 Supplemental Corrective Actions

(Continued)

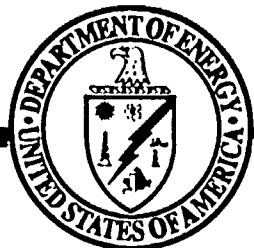
- **Action #3: Revise 5 Model Reports judged as “Unsatisfactory” by DOE/OQA Verification Review Team** (Continued)
 - BSC Quality Assurance has verified the 4 completed Model Reports are adequate
 - 5th model (*Stress Corrosion Cracking of Drip Shield, Waste Package Outer Barrier and Stainless Steel Structural Material*): Approval expected February 20, 2004



Next Steps

- **BSC will formally request DOE/OQA verification and closure of CR 99 when corrective actions are complete**
- **DOE/OQA Action: R. Hasson will summarize**





U.S. Department of Energy
Office of Civilian Radioactive Waste Management



Office of Quality Assurance Verification Status for Model Validation Condition Report 099 (BSC-01-C-001)

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Robert P. Hasson
Program Manager, Navarro Quality Services
Office of Civilian Radioactive Waste Management
Department of Energy

Washington, D.C.
November 15, 1999

Status Model Validation

- **Office of Quality Assurance (OQA) verification activities complete for 11 of 12 corrective actions**
- **Significant improvement in validation for model Analysis Model Reports (AMRs) noted during previous BSC model status review**
- **Verification plans for remaining action:**
 - **OQA will perform a 100 percent verification of remaining model AMRs in accordance with AP-SIII.10Q, Models (Section 5.3)**

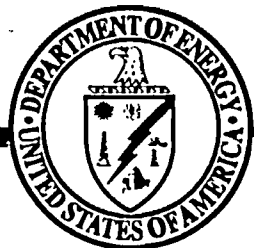


Status Model Validation

(Continued)

- **Verification of validation compliance for 5 AMRs determined to be unsatisfactory during recent CR-099 verification by OQA**
- **Verification of BSC self-assessment to determine the need for improvements to AP-SIII.10Q or any other actions necessary to preclude recurrence**





U.S. Department of Energy
Office of Civilian Radioactive Waste Management



Data Management and Qualification

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Michael A. Jaeger
Management Systems
Bechtel SAIC Company, Inc.



Data Condition Report 16 Status

(CAR BSC-03-C-107)

- **Issue:**
 - Recurring data deficiencies
- **Actions:**
 - Root Cause Analysis completed
 - Management leadership/data terminology
 - Procedures modified
 - Remedial Action Plan completed
- **BSC Quality Assurance Verification of Actions**



Remediation of Technical Products

- **Actions:**
 - Evaluate each product for procedure compliance
 - ♦ Phase I review covers product compliance and is completed during checking/review
 - ♦ Phase II review covers legacy data issues and is completed on approved products
 - ♦ Remediation Plan input provided to author for evaluation
- **Data Confirmation Reviews:**
 - Approximately 150 technical products
 - 110 (73 percent) products have completed Phase I review
 - 33 (22 percent) products completed Phase II review
 - 33 (22 percent) products have completed remediation plan inputs



Data Management and Qualification

- **Assigned additional staff to resolve data qualification issues**
- **Data Tracking Numbers (DTNs) upgraded to fully qualified status during the quarter**
- **Procedures modified**
 - **New data submittals**
- **Completion of data qualification**



Data Verification

- **Documentation review**
- **Review traceability from first records to Technical Data Management System (TDMS)**
- **Procurement issues**
 - **Analytical services**
 - **Calibration services**
- **Software qualification**

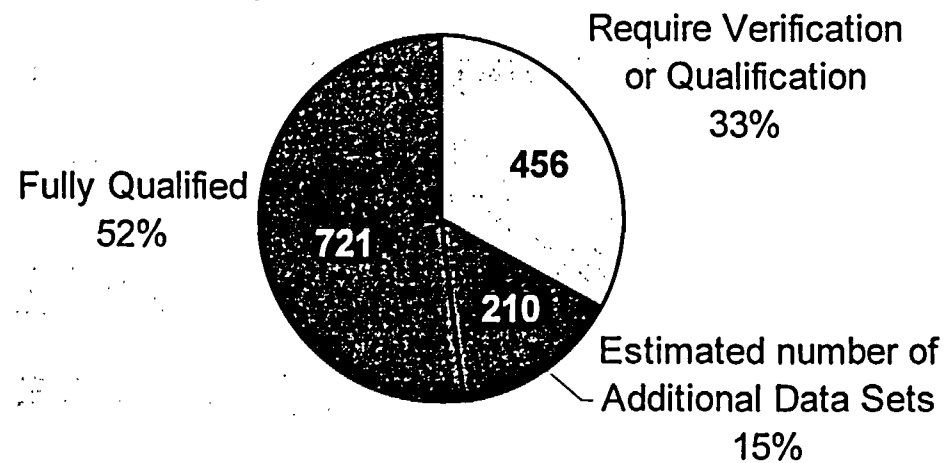


Qualification of Data

- **A formal process that is intended to provide a desired level of confidence that data is suitable for its intended use**
 - **Plan**
 - **Select method(s)**
 - **Evaluate**
 - **Document**

Metrics

Data Sets Supporting LA



Total Number of DTNs
Cited: 1387
(As of 12/31/03)



Actions to Accelerate Data Qualification Effort

- **Analysis Model Report (AMR) Review Team**
 - Involvement of Line/Additional staff
 - Dedicated team on AMR
- **Verification Staff**
 - Additional Staff
 - Working large, complex datasets first
 - 152 of 227 DTN verification roadmaps started





U.S. Department of Energy
Office of Civilian Radioactive Waste Management



Software Development (CR-102) (CAR BSC-01-C-002)

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Richard A. Atkisson
Manager, Mission Applications
Bechtel SAIC Company, LLC

February 18, 2004
Rockville, Maryland

Corrective Action Report (CR-102)

(CAR BSC-01-C-002)

- **Corrective Action Report (CAR) CAR-002 Issues:**
 - **Ineffective implementation of software management requirements**
 - **Corrective actions include:**
 - ♦ **Procedure revisions/development**
 - ♦ **Training and requirements emphasis**
 - ♦ **Management Improvement Activities**
 - **Corrective actions to be complete March 2004**



Status of CAR-002 Actions

- **CAR-002 Actions:**
 - Request for verification received by Office of Quality Assurance on (OQA) September 11, 2003
 - 23 of 28 actions are complete and verified as satisfactory by OQA
 - 5 actions verified as unsatisfactory and returned for rework
 - ♦ 3 actions related to consistency/clarity in software development portion of software package
 - » Procedure revision is complete and training is being developed with an estimated effective date of February 24, 2004
 - » 1 action related to timeliness of software defect impact analysis - included in procedure revision effective February 24, 2004
 - » 1 action related to Legacy software testing - Legacy software testing procedure (AP-SI.4Q) has been developed and approved



Status of CAR-002 Actions

(Continued)

- **CAR-002 Actions (Continued):**
 - ♦ Legacy software functionality testing is in progress
 - Software performance-based audit in June 2003 confirmed the need for software development procedure changes
 - ♦ Impact: To date no adverse impact on code functionality or technical products has been noted
 - ♦ Amended response required for 5 open actions complete and accepted by OQA which includes CRs 46, 48, and 76 (formerly Deficiency Reports (DRs) 177, 178, 179)



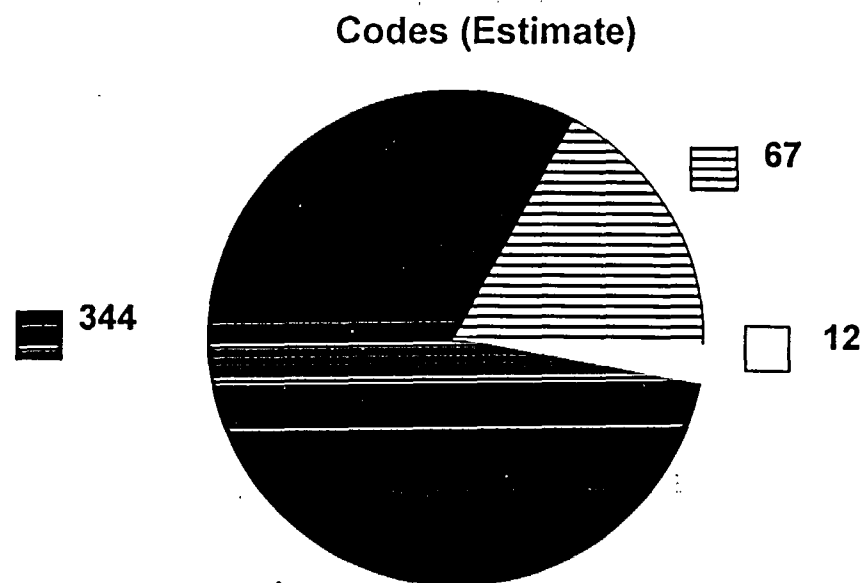
Legacy Software Retest

- **423 baselined software codes will be used in support of License Application (LA) (as of February 9, 2004)**
 - Those codes baselined prior to January 13, 2003 (Legacy Software) will be retested
 - Retest is for code functionality and consists of software installation and validation tests
 - Retest is governed by procedure:
 - ♦ *AP-SI.4Q - Independent Verification and Validation of Legacy Code*
- **124 software codes have been qualified/completed retest (as of February 9, 2004)**
- **100 codes are in process/undergoing Independent Verification and Validation (IV&V) as of February 9, 2004**






Metrics

(Counts as of February 9, 2004)



Total Codes: 423

-  Qualified & Verified: 67 (16%)
-  Qualified (Legacy/re-testing): 344 (81%)
-  Developing/verifying: 12 (3%)





U.S. Department of Energy
Office of Civilian Radioactive Waste Management



Office of Quality Assurance Verification Status for Software Condition Report 102 (BSC-01-C-002)

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
Robert P. Hasson
Program Manager, Navarro Quality Services
Office of Civilian Radioactive Waste Management
U.S. Department of Energy

February 19, 2002
Rockville, Maryland

Software

- **28 Corrective action commitments**
- **23 have been satisfactorily verified by the Office of Quality Assurance (OQA)**
- **3 Commitments remain open (BSC actions in progress at this time)**
- **2 in OQA for verification**



Software

(Continued)

- **3 Commitments associated with Software Procedures**
 - Procedures are currently in formal review process
 - OQA to review procedures for Quality Assurance Requirements and Description (QARD) compliance
- **1 Commitment to address Impact Analyses for Software Problem Reports**
 - OQA to verify 17 Software Problem Reports for completion of Impact Analyses (in OQA for verification)



Software

(Continued)

- **1 Commitment to address Legacy Software re-testing**
 - OQA to sample approximately 25 test packages for procedure compliance (AP-SI.4Q) (in OQA for verification)
- **Additionally, verify corrective actions for software audit findings (Condition Reports 46, 48, and 76)**
 - Verify remedial actions
 - OQA to sample 25 software code packages





U.S. Department of Energy
Office of Civilian Radioactive Waste Management



Software Quality Assurance

Presented to:
DOE/NRC Quarterly Quality Assurance Meeting

Presented by:
R. Dennis Brown
Director, Office of Quality Assurance
Office of Civilian Radioactive Waste Management
U.S. Department of Energy



Software Quality Assurance

- **Software Use**
- **Software Surveillance Conclusions**
- **Independent Evaluation of Software Issues**



YUCCA MOUNTAIN PROJECT



U.S. Department of Energy
Office of Civilian Radioactive Waste Management



Quality Assurance Audits

Presented to:

DOE/NRC Quarterly Quality Assurance Meeting

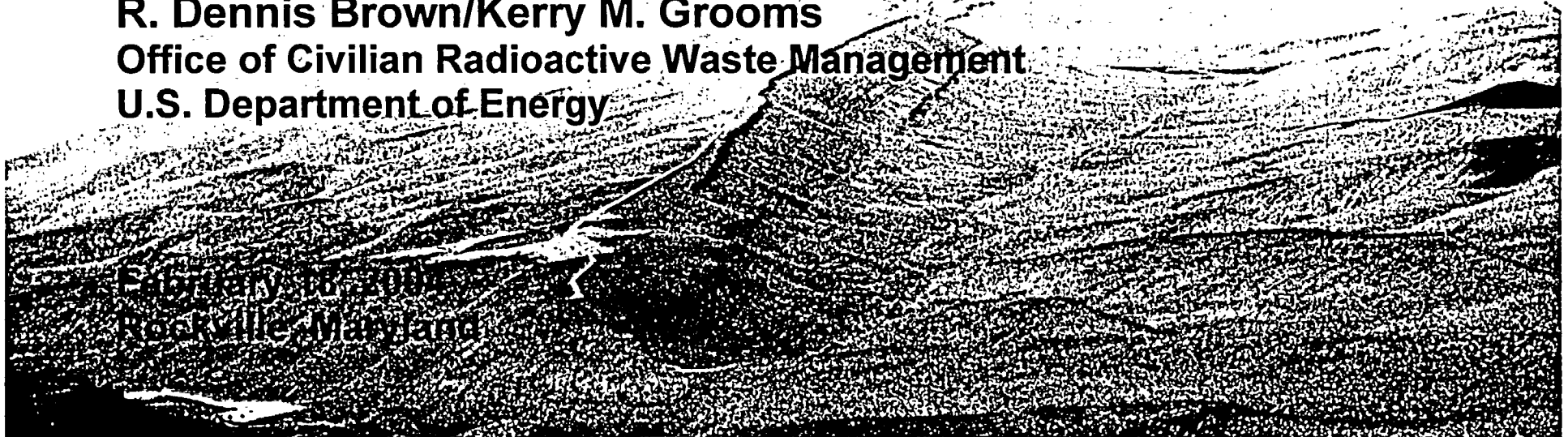
Presented by:

R. Dennis Brown/Kerry M. Grooms

Office of Civilian Radioactive Waste Management

U.S. Department of Energy

**February 18, 2004
Rockville, Maryland**



Environmental Management Audits

- **Condition Report EM-01-D-089**
 - **Condition - Memorandum of Agreement between Environmental Management (EM) and OCRWM did not reflect current EM organization**
 - **Corrective Actions**
 - ♦ **Roles and Responsibilities Memo - Signed December 19, 2003**
 - ♦ **Procedure AP-18.4Q, *DOE EM/RW Oversight Process* - Effective December 19, 2003**
 - **Condition Report Closed - December 29, 2003**



YUCCA MOUNTAIN PROJECT

Environmental Management Audits

(Continued)

- **Condition Report 97**
 - **Condition - Required oversight has not been performed at Savannah River Site, National Spent Nuclear Fuel (SNF) Program, and Office of River Protection**
 - **Corrective actions:**
 - ♦ **Develop Audit Schedule**
 - ♦ **Perform Audits - First audit March 2004**



YUCCA MOUNTAIN PROJECT

Environmental Management Audits

(Continued)

EM Audit Schedule

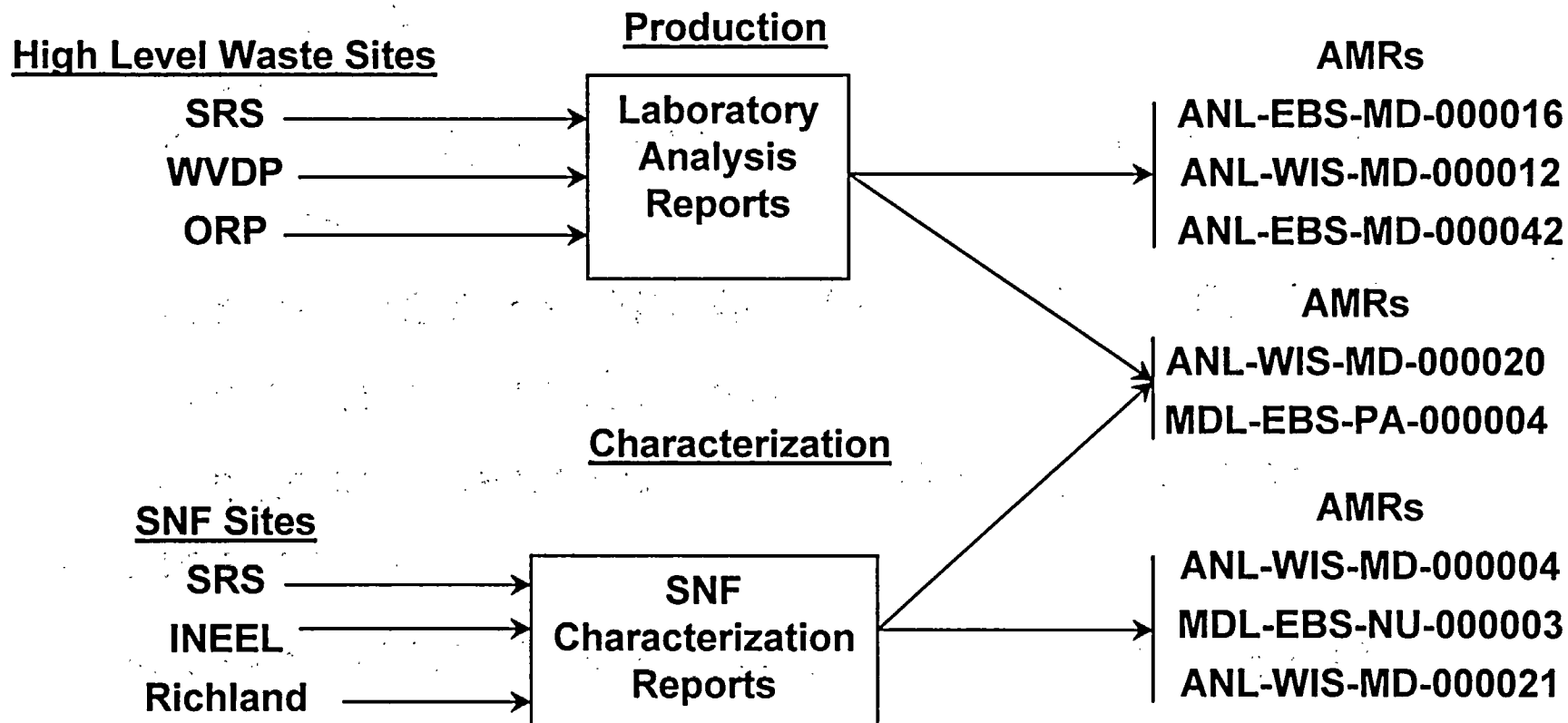
Audit Date	Organization to be Evaluated	Location
March 2004	National Spent Nuclear Fuel Program (SNF)	Idaho Falls, ID
April 2004	Savannah River Site (SRS) Defense Waste Processing Facility (High Level (radioactive) Waste (HLW))	Aiken, SC
May 2004	West Valley Demonstration Project (HLW)	West Valley, NY
June 2004	Idaho National Engineering and Environmental Laboratory (SNF)	Idaho Falls, ID
July 2004	Office of River Protection-Hanford (HLW)	Richland, WA
August 2004	Hanford (SNF)	Richland, WA
September 2004	SRS (SNF)	Aiken, SC



Environmental Management Audits

(Continued)

High Level Waste/DOE Spent Nuclear Fuel Feeds to Total System Performance Assessment (TSPA)



Quality Assurance Audits

- **Internal Audits Completed - 1st Quarter FY 04**
 - **Procedures**
 - ♦ **6 Conditions Adverse to Quality (CAQs) Identified**
- **Surveillances Completed**
 - **BQA-SI-04-032 - Evaluation of Design Calculations**
 - ♦ **No CAQs**
 - **BQA-SI-04-030 - Evaluation of System Description Documents**
 - ♦ **No CAQs**



Quality Assurance Audits

(Continued)

- **Surveillances Completed**
 - **OQA-SI-04-008 - The Usage and Control of Software Yet To Be Qualified**
 - ♦ **3 CAQs**
- **Surveillances in progress**
 - **BQA-SI-04-048 - Independent Technical Evaluation of Model Development and Validation**
 - **BQA-SI-04-014 - Legacy Software Verification and Validation**
 - **BQA-SI-04-002 - Analysis Reports per AP-SIII.9Q, *Scientific Analyses***
 - **BQA-SI-04-012 - Corrective Action Program (CAP) Evaluation process**



Surveillance OQA-SI-04-003

- **Evaluated BSC procurement actions for one task on one contract**
 - Task was to design and prototype the Waste Package Closure System
 - Work was not associated with Environmental Management Spent Nuclear Fuel or High Level Waste
 - Three CAQs identified
 - BSC directed supplier to suspend work
 - Product already received (drawings) was placed on hold



Surveillance OQA-SI-04-003

(Continued)

- **Condition Report 1712**
 - Procurement document not prepared per procedure
- **Condition Report 1714**
 - Survey of supplier Quality Assurance (QA) program not in accordance with procedure
- **Condition Report 1720**
 - Survey of supplier QA Program not performed
 - Supplier was not placed on the Qualified Suppliers List
 - Quality affecting work was being performed



Quality Assurance Audits

Internal Audit Schedule

Audit Dates	Audit Description	Lead Organization
February 2004	Compliance Audit of BSC Records Management	BSC
April 2004	Compliance Audit of BSC Procurement	BSC
April 2004	Compliance Audit of LLNL	BSC
May 2004	Compliance Audit of LANL	BSC
May 2004	Compliance Audit of USGS	BSC
June 2004	Compliance Audit of Corrective Action Program	OQA
July 2004	Compliance Audit of LBNL	BSC
July 2004	Compliance Audit of SNL	BSC
July 2004	Performance-Based Audit of BSC Performance Assessment	OQA
August 2004	Compliance Audit of OQA	OQA
August 2004	Compliance Audit of ORD	OQA



Consolidated Action Items
From The
NRC/DOE Quarterly QA Meetings
 (February 18, 2004)

Item No.	Description	Status
QA-0311-01	Provide additional information on the screening team for causal codes and their function to NRC OR Office.	Proposed Complete. The NRC OR was briefed on the screening team and the causal codes and their function on January 27, 2004. In addition a Condition Report (CR-1816) is being processed on this area.
QA-0311-02	Provide an update on closure of CAR-001 on Model Validation to the NRC OR prior to the next QA meeting, and also discuss during the next QA meeting.	Proposed Complete. The NRC OR was briefed on the closure status of CAR-001 on Model Validation on February 10, 2004 and the subject is also being discussed at the February 18, 2004 QA Meeting.
QA-0311-03	Provide additional information to NRC OR on the Procedural Compliance Trend Report (exhibit in Management Meeting Project Update presentation) - how the human performance is integrated into Corrective Action Program.	Proposed Complete. Human performance issues are on the agenda for the February 18, 2004 QA Meeting. The NRC OR was also briefed on January 26 and February 12, 2004.
QA-0311-04	Provide the OQA interpretation of "use" of software to NRC OR	Proposed Complete. OQA issued a letter to BSC on February 3, 2004 providing the interpretation of "use" of software. This interpretation has been discussed with the OR and will be discussed during the February 19, 2004 QA Meeting.
QA-0311-05	Provide feedback on audit of EM sites during the next QA Meeting	Proposed Complete. A discussion of audits of EM sites is on the agenda for the February 18, 2004 QA Meeting.
QA-0311-06	Explain the feeds and make-up of performance indicators for QA to the NRC OR	Proposed Complete. The NRC OR was provided on the feeds and make-up of QA performance indicators on February 4, 2004.
QA-0311-07	Provide information during the next QA Meeting on how to determine the effectiveness of the training for root cause analysis	Proposed Complete. Effectiveness reviews are on the agenda as part of the Corrective Action Program discussion at the February 18, 2004 QA Meeting.

QA-0311-08	Provide additional information to NRC OR on model validation and the models determined to be inadequate	Proposed Complete. The NRC OR was briefed on model validation and models determined to be inadequate on February 10, 2004. Completion is pending planned discussion at the February 18, 2004 QA Meeting.
QA-0311-09	Provide additional information to NRC OR on how instances of recurring issues and ineffectiveness of corrective actions are identified in trending program	Proposed Complete. Procedure AP-16.3Q on trending and the use of the trending program to identify recurring issues and potentially ineffective corrective actions have been the subject of a series of discussions between the QA organization and the NRC OR. The trending program is also the subject of an agenda item for the February 18, 2004 QA meeting.

Note: The Quarterly QA Meeting action items are designated as "QA yymm-nn" where yy is a two digit year, mm is a two digit month and nn is a two digit action item number from that meeting.